الجامعة الأردنيـــــة
كلية الدراسات العليا

التاريـــخ: / /

نموذج رقم (١٨)
اقرار والتزام بالمعايير الأخلاقية والأمانة العلمية
وقوانين الجامعة الأردنية وأنظمتها وتعليماتها
لطلبة الماجستير

أنا الطالب: محمد خلف ادويب الرقم الجامعي: (4090535)
تخصص: الصيدلة السريرية الكليـــــــة: الصيدلة

عنوان الرسالة: Impact of clinical pharmacist intervention on health outcomes in patients with diabetes mellitus

اعلن بأنني قد التزمت بقوانين الجامعة الأردنية وأنظمتها وتعليماتها وقراراتها السارية المفعول المتعلقة باعداد رسائل الماجستير عندما قمت شخصيا" باعداد رسالتي وذلك بما ينسجم مع الأمانة العلمية وكافة المعايير الأخلاقية المتعارف عليها في كتابة الرسائل العلمية. كما أنني أعلن بأن رسالتي هذه غير منقولة أو مستلة من رسائل أو كتب أو أبحاث أو أي منشورات علمية تم نشرها أو تخزينها في أي وسيلة اعلامية، وتأسيسا" على ما تقدم فانني أتحمل المسؤولية بأنواعها كافة فيما لو تبين غير ذلك بما فيه حق مجلس العمداء في الجامعة الأردنية بالغاء قرار منحي الدرجة العلمية التي حصلت عليها وسحب شهادة التخرج مني بعد صدورها دون أن يكون لي أي حق في التظلم أو الاعتراض أو الطعن بأي صورة كانت في القرار الصادر عن مجلس العمداء بهذا الصدد.

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IMPACT OF CLINICAL PHARMACIST INTERVENTION ON HEALTH OUTCOMES IN PATIENTS WITH DIABETES MELLITUS

By

Mohammad Khalaf Dweib

Supervisor

Dr Nailya Bulatova

Co-supervisor

Dr Salah AbuRuz

Co-supervisor

Dr Ayman Zayed

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COMMITTEE DECISION

This thesis (Impact of Clinical Pharmacist intervention on health outcomes in patients with diabetes mellitus) was successfully defended and approved on 26/6/2011.

<u>**Examination committee**</u>	<u>**Signature**</u>
Dr. Nailya Bulatova (Supervisor) Assoc. Prof. of Pharmacology and Pharmacotherapy	....
Dr. Salah M. AbuRuz (Co-Supervisor) Assoc. Prof. of Clinical Pharmacy and Pharmacotherapy	....
Dr. Ayman A. Zayed (Co-Supervisor) Assoc. Prof. of Diabetes and Endocrinolgy	....
Dr. Abla Albsoul-Younes (Member) Professor of Pharmacology and Pharmacotherapy	....
Dr. Mohammad Khalil (Member) Medicinal and Biological Chemistry	....
Dr. Iman A. Basheti (Member) Assist. Prof. of Clinical Pharmacy (Applied Science Private University)	....

Dedication

To

My family

My father, mother

My brother

Not everyone is lucky enough to have a wonderful family like you.

Acknowledgement

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Abbreviation	
ADA	American diabetes association
ADR	Adverse drug reaction
ACEI	Angiotensin converting enzyme inhibitor
ARB	Angiotensin receptor blocker
CVD	Cardiovascular disease
CAD	Coronary artery disease
DRP	Drug related problem
DM	Diabetes mellitus
FBG	Fasting blood glucose
HbA1c	Glycosylated hemoglobin
HDL	High density lipoprotein
IGT	Impaired glucose tolerance
IFG	Impaired fasting glucose
LDL	Low density lipoprotein
OGTT	Oral glucose tolerance test
QoL	Quality of life
SDSCA	Summary of diabetes self care activities
TRP	Treatment related problem
DCCT	Diabetes Control and Complications Trial
UKPDS	United Kingdom Prospective Diabetes Study
GDM	Gestational diabetes mellitus

SMBG	self-monitored blood glucose
EASD	European Association for the Study of Diabetes
VAHCS	Veterans Affairs Health Care System
POD	point-of-dispensing

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Abstract

Poor control on diabetes remains an important national health concern as the prevalence of diabetes and its complications is significantly increasing. The prevalence of diabetes in Jordan has increased dramatically over the period 1994-2004, so patients are likely to benefit from any programs that aim at improving control over diabetes and its complications.

The role of clinical pharmacist in the management of diabetes has been evaluated by many studies. Those previous studies involved small samples, were nonrandomized, targeted at particular patient groups such as insulin-treated type 2 subjects, older patients, and those with a

relatively high HbA1C, and/or did not recruit a contemporary control group, while others did not report glycemic outcomes or adjust for baseline differences in glycemic variables between intervention and control. The aim of this study was to determine the impact of clinical pharmacists involved in direct patient care on the glycemic control, cardiovascular and other clinical outcomes of patients with type 2 diabetes mellitus in a public university hospital.

The major end result of this prospective, randomized controlled study is that Clinical Pharmacist intervention led to a significant improvement in patients' health outcomes such as HbA1c, FBG, and adherence to medications and life style modifications.

Impact of Clinical Pharmacist intervention on health outcomes in patients with diabetes mellitus

1. Introduction

Diabetes mellitus (diabetes, DM), as defined by the American Diabetes Association (ADA) is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both (American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, 2010).

According to the 2011 National Diabetes Fact Sheet, 25.8 million children and adults in the United States (8.3% of population) have DM.

In Jordan, the prevalence of DM is much higher: the overall prevalence of DM is 17.1; in addition, impaired glucose tolerance (IGT) was found in 7.8% of the study population (Ajlouni, *et al.,* 2007)

Chronic hyperglycemia of DM is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels. This is a consequence of deficit in insulin actions on target tissues as a result of inadequate insulin secretion and/or diminished tissue responses to insulin at one or more points in the complex pathways of hormone action. (American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, 2010).

Long-term complications of diabetes include retinopathy with potential loss of vision; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers and amputations; and autonomic neuropathy causing gastrointestinal, genitourinary and cardiovascular symptoms and sexual dysfunction. Patients with diabetes have an increased incidence of atherosclerotic cardiovascular, peripheral arterial and cerebrovascular disease. Hypertension and abnormalities of lipoprotein metabolism are often found in people with diabetes (American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, 2010).

These complications can be reduced by adequate control of blood glucose as illustrated by the Diabetes Control and Complications Trial (DCCT) (Diabetes Control and Complications Trial Research Group, 1993) and the United Kingdom Prospective Diabetes Study (UKPDS: United Kingdom Prospective Diabetes Study, 1995), which demonstrated that glycosylated hemoglobin levels less than 7% reduced the development of certain DM complications.

The DCCT, a prospective, randomized, controlled trial of intensive versus standard glycemic control in patients with relatively recently diagnosed type 1 diabetes, showed association between improved glycemic control and decreased rates of microvascular (retinopathy and nephropathy) and neuropathic complications. The UKPDS demonstrated similar results with intensive therapy. However, in these studies, the potential of intensive glycemic control to reduce CVD has been less clear. In the DCCT, there was a trend toward lower risk of CVD events with intensive control, but the number of events was small. However, 9-year post-DCCT follow-up of the cohort has shown that subjects previously randomized to the intensive therapy arm had a 42% reduction in CVD outcomes and a 57% reduction in the risk of nonfatal MI, stroke, or CVD death compared with subjects randomized previously to the standard treatment arm.

The UKPDS trial of type 2 diabetes observed a 16% decrease in CV complications (combined fatal or nonfatal MI and sudden death) in the intensive glycemic control arm, although this difference was not statistically significant (*P*= 0.052), and there was no suggestion of benefit on other CVD outcomes such as stroke. (UKPDS: United Kingdom Prospective Diabetes Study, 1995; ADA Standards of Medical Care in Diabetes 2010).

Despite the awareness of the harmful consequences of diabetes, and the introduction of new classes of antidiabetic agents, the efforts to achieve a better control on diabetes are disappointing and unsatisfactory (Luna and Ferlingos, 2001).

Adherence of health care providers to evidence-based pharmacotherapy is one of the most important factors to control diabetes. But unfortunately, there appears to be a wide gap between recommendations and actual practice (Ragucci, *et al*., 2005).

This study intended to evaluate the role of a Clinical Pharmacist as a member of the healthcare team in improving the management of diabetic patients through several aspects.

1.1 Diabetes Mellitus:

1.1.1 Classification of diabetes:

- According to ADA, diabetes can be classified into one of four major categories (American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

:

- Type 1 diabetes: results from beta-cell destruction, usually leading to absolute insulin deficiency.

- Type 2 diabetes: results from a progressive insulin secretory defect associated with insulin resistance.

- Other specific types of diabetes due to other causes, e.g., genetic defects in Beta-cell function, genetic defects in insulin action, diseases of the exocrine pancreas (such as cystic fibrosis), and drug or chemical-induced diabetes (such as in the treatment of AIDS or after organ transplantation).

- Gestational diabetes mellitus (GDM) (diabetes diagnosed during pregnancy)

1.1.2 Diagnosis of diabetes:

In its 2010 recommendations, the ADA has modified its criteria for diagnosis of diabetes to add glycosylated hemoglobin (HbA1c) value of more than 6.5 % as a cut point for diagnosis of diabetes mellitus, which they found to be an inflection point for retinopathy prevalence (American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

Currently, the criteria for diagnosis of diabetes include:

1- HbA1c ≥6.5% OR

2- Fasting plasma glucose (FPG) ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h OR

3- 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water OR

4- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dl (11.1 mmol/l) (American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

1.1.3 Increased risk for diabetes:

Individuals with Impaired Fasting Glucose (IFG) and/or Impaired Glucose Tolerance (IGT) have been referred to as having pre-diabetes, indicating the relatively high risk for the future development of diabetes.

(IFG) is having FPG levels of 100 mg/dl [5.6 mmol/l] to 125 mg/dl [6.9 mmol/l], while IGT is a 2-h OGTT values of 140 mg/dl [7.8 mmol/l] to 199 mg/dl [11.0 mmol/l].

IFG and IGT should not be viewed as clinical entities in their own but rather as risk factors for diabetes as well as cardiovascular disease (CVD) (American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

1.1.4 Cardiovascular risk:

CVD is the major cause of morbidity and mortality for diabetics and the largest contributor to the direct and indirect costs of diabetes. The common conditions coexisting with type 2 diabetes (e.g., hypertension and dyslipidemia) are clear risk factors for CVD, and diabetes itself is considered as an independent risk (American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

Among type 2 diabetic patients, the incidence of myocardial infarction or stroke is increased two- to threefold and the risk of death is double, even after correction for other known cardiovascular risk factors, suggesting that some features of diabetes must confer such an excessive propensity toward CVD (Bianchi, *et al.,* 2008).

From an epidemiological point of view, there is evidence that the risk of cardiovascular mortality is increased with the increase of blood glucose concentrations and A1C levels. (Riddle, *et al*., 2010).

1.1.5 Treatment of diabetes:

Appropriate care requires goal setting for glycemia, blood pressure, and lipid levels, regular monitoring for complications, dietary and exercise modifications, medications, appropriate self-monitored blood glucose (SMBG), and laboratory assessment of the aforementioned parameters. (American Diabetes Association, 2004).

1.1.5.1 Desired outcomes of diabetes treatment:

The primary goals of DM management are to reduce the risk for microvascular and macrovascular disease complications, to improve symptoms, to reduce mortality, and to improve quality of life. Near-normal glycemia will reduce the risk for development of microvascular disease complications, but aggressive management of traditional CV risk factors (i.e., smoking cessation, intensive blood pressure control, treatment of dyslipidemia, and antiplatelet therapy) are essential to reduce the likelihood of development of macrovascular disease (American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

The glycemic goals that have been shown to be associated with a reduction in microvascular and macrovascular complications are:

HbA1C	< 7%
Preprandial capillary plasma glucose	70-130 mg/dl
Peak postprandial capillary plasma glucose	<180mg/dl

(American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

The goal for blood pressure in patients with diabetes is lower than 130/80, and hypertension therapy should contain either an angiotensin converting enzyme inhibitor (ACEI), or an angiotensin II receptor blocker (ARB) (American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

Concerning dyslipidemia, the ADA 2010 guidelines recommend a primary goal of LDL cholesterol <100 mg/dl (2.6 mmol/l) in individuals without overt CVD, while in individuals with

overt CVD, a lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/l) is an option. (American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

Triglycerides levels <150 mg/dl (1.7 mmol/l) and HDL cholesterol > 40 mg/dl (1.0 mmol/l) in men and > 50 mg/dl (1.3 mmol/l) in women, are desirable (American Diabetes Association, Standards of Medical Care in Diabetes, 2010).

1.1.5.2 Non-pharmacologic treatment:

Medical nutrition therapy is suggested for all persons with DM. Paramount for all medical nutrition therapy is the accomplishment of optimal metabolic outcomes and the prevention and treatment of complications. For individuals with type 1 DM, the focus is on regulating insulin administration with a balanced diet to attain and maintain a healthy body weight. A meal plan that is moderate in carbohydrates and low in saturated fat (<7% of total calories), with a focus on balanced meals is recommended. (American Diabetes Association, Nutrition Recommendations and Interventions for Diabetes, 2007). In addition, patients with type 2 DM often require caloric restriction to encourage weight loss, as most patients with type 2 DM are overweight or obese.

In general, most patients with DM can profit from increased activity. Physical activity goals include at least 150 minutes/week of moderate (50%–70% maximal heart rate) intensity exercise. In addition, resistance training, in patients without retinal contraindications, is recommended for 30 minutes three times per week (American Diabetes Association, Diabetes Mellitus and Exercise, 2004).

1.1.5.3 Pharmacologic therapy:

Early management with lifestyle modification in addition to metformin, and subsequent intensification of therapy with other available antidiabetic agents to achieve and maintain glycemic goals is recommended by the consensus statement published by the ADA and European Association for the Study of Diabetes (EASD) (Nathan, *et al.,* 2006). It is summarized in Figure 1:

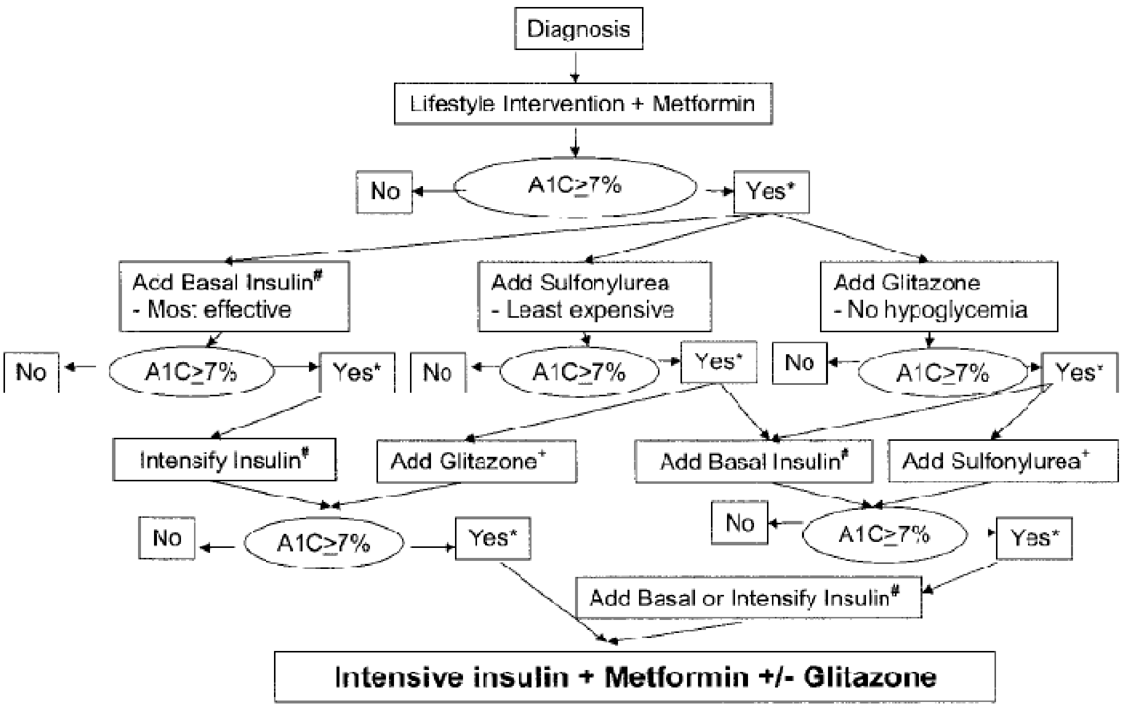


Figure 1. Algorithm for the metabolic management of type 2 diabetes (Nathan, *et al.,* 2006),

The Statement also summarizes the available antidiabetic medications with their expected benefits as monotherapy (Table 1).

Table 1. Summary of antidiabetic interventions as monotherapy (Nathan, *et al.*, 2006).

Interventions	Expected decrease in A1c	Advantages	Disadvantages
Step 1: initial Lifestyle to decrease weight and increase activity	1-2	Low cost, many benefits	Fails for most in 1st year
Metformin	1.5	Weight neutral, inexpensive	GI side effects, rare lactic acidosis
Step 2: additional therapy Insulin	1.5-2.5	No dose limit, inexpensive, improved lipid profile	Injections, monitoring, hypoglycemia, weight gain
Sulfonylureas	1.5	Inexpensive	Weight gain, hypoglycemia*
TZDs	0.5-1.4	Improved lipid profile	Fluid retention, weight gain, expensive
alpha-Glucosidase inhibitors	0.5-0.8	Weight neutral	Frequent GI side effects, three times/

			day dosing, expensive
Exenatide	0.5-1.0	Weight loss	Injections, frequent GI side effects, expensive, little experience
Glinides	1.0-1.5†	Short duration	Three times/day dosing, expensive
Pramlintide	0.5-1	Weight loss	Injections, three times/day dosing, frequent GI side effects, expensive, little experience

*Severe hypoglycemia is relatively infrequent with sulfonylurea therapy. The longer-acting agents (e.g. chlorpropamide, glyburide (glibenclamide), and sustainedrelease glipizide) are more likely to cause hypoglycemia than glipizide, glimepiride, and gliclazide. †Repaglinide is more effective at lowering A1C than nateglinide.

GI, gastrointestinal.

A brief discussion of the hypoglycemic medications follows below.

1.1.5.3.1 Metformin

In the absence of contraindications, metformin is the first choice for oral treatment of type 2 diabetes. In the UKPDS, treatment with metformin resulted in significant risk reductions for any diabetes-related endpoint (endpoints included both macrovascular and microvascular complications), as a 10 year follow up of the patients randomized to the intensive therapy arm of the study have shown that metformin as an initial therapy led to 33% reduction in MI compared to 15% with sulfonylurea or insulin as initial pharmacotherapy. (UKPDS: United Kingdom Prospective Diabetes Study, 1995).

Metformin generally reduces A1C by 1.5 percentage points. (DeFronzo, *et al.*, 1995). Metformin is effective only in the presence of insulin, and its major effect is decreasing hepatic glucose output (Bailey, *et al.,* 1996). In contrast to most other antidiabetic drugs which cause an increase in body weight, metformin use often causes either stabilization in the body weight or even a small reduction in it (Hermann, *et al*., 1994).

The most common side effects of metformin are gastrointestinal, such as a metallic taste in the mouth, nausea, anorexia, abdominal discomfort, and diarrhea. These symptoms are usually mild, transient, and reversible after dose reduction or discontinuation of the drug. In clinical trials, only 5 percent of study subjects stop metformin because of the gastrointestinal side effects (Bailey, *et al*., 1992).

Metformin may cause a decrease in absorption of vitamin B12 in up to 30 percent of subjects, and lowers serum vitamin B12 concentrations in 5 to 10 percent, but only rarely causes

megaloblastic anemia. This effect is proportional to the dose and duration of metformin use (Ting, *et al*., 2006).

1.1.5.3.2 Sulfonylureas:

Sulfonylureas are the most widely used drugs for the management of patients with type 2 diabetes. The net effect of their action is increased responsiveness of beta cells to both glucose and non-glucose secretagogues (such as amino acids), resulting in more insulin release at all blood glucose concentrations. Thus, sulfonylureas can only be useful in subjects with residual beta cell function. Sulfonylureas may work extra-pancreatically by increasing insulin sensitivity in peripheral tissues (Bressler, *et al*., 1997).

Sulfonylureas usually lower blood glucose concentrations by about 20 percent and A1C by 1 to 2 percent points. (Bressler *et al*. 1997; Hermann *et al*., 1994).

Sulfonylureas have negligible side effects. Hypoglycemia is the most common side effect and is more common with long-acting agents (such as chlorpropamide and glyburide) (Holstein, *et al*., 2001; Gangji, *et al*., 2007).

1.1.5.3.3 Meglitinides:

The meglitinides, repaglinide and nateglinide, are short-acting hypoglycemic drugs for therapy of patients with type 2 diabetes alone or in combination with metformin. They differ from sulfonylureas in structure and exert effect by binding to different receptors, but act similarly by regulating ATP-dependent potassium channels in pancreatic beta cells, thereby increasing insulin secretion (Fuhlendorff, *et al*., 1998).

The clinical efficacy of meglitinide monotherapy is similar to that of the sulfonylureas (Wolffenbuttel, *et al*., 1999; Hollander, *et al*., 2001).

1.1.5.3.4 Thiazolidinediones:

The thiazolidinediones increase insulin sensitivity by acting on adipose tissue, muscle, and liver to increase glucose utilization and reduce glucose production. (Iwamoto *et al*., 1996; Yki-Jarvinen, 2004).

As monotherapy, thiazolidinediones are less efficacious in reducing blood glucose, lowering A1C by 0.5 to 1.4 percentage points. (Schernthaner, *et al*., 2004)

All of the thiazolidinediones cause weight gain. It is both dose-dependent and time-dependent and can be substantial and is mainly caused by fluid retention. (InzucchI, *et al*., 1998).

1.1.5.3.5 Glucagon-like peptide 1 agonists:

Exenatide and liraglutide are glucagon-like peptide 1 (GLP-1) analogs which are administered subcutaneously. GLP-1 exerts its main effect by stimulating glucose-dependent insulin secretion from the pancreatic islets. It restores both first phase and second phase insulin response to glucose. Exenatide (requires two daily injections) or liraglutide (one daily injection) could be considered as add-on drugs for patients with type 2 diabetes who are not controlled on maximal doses of one or two oral agents (Fehse, *et al*., 2005).

1.1.5.3.6 Alpha-glucosidase inhibitors:

Taken orally, they inhibit the upper gastrointestinal enzymes (alpha-glucosidases) that break complex polysaccharide carbohydrates into monosaccharide subunits in a dose-dependent fashion. These drugs slow absorption of glucose; the slower rise in postprandial blood glucose concentrations is potentially beneficial in both type 1 and type 2 diabetes. In older patients with type 2 diabetes, acarbose may also improve insulin sensitivity (Meneilly, *et al.,* 2000).

In a meta-analysis of 41 trials of alpha-glucosidase inhibitor therapy (primarily acarbose trials), beneficial effects were seen (compared to placebo) on A1C (-0.77 percentage points), fasting, and postload glucose and postload insulin levels (van de Laar, *et al*., 2005).

1.1.5.3.7 Insulin:

Insulin is the oldest of the currently available medications and has the most clinical experience. Insulin is the most successful of diabetes medications in lowering blood glucose. It can, when used in adequate doses, decrease any level of elevated A1C to, or near, the therapeutic goal. In contrast to other antidiabetic medications, insulin has no maximum dose after which its efficacy is not increased by increasing the dose. Relatively large doses of insulin (≥1 unit/kg), compared with those required to treat type 1 diabetes, may be needed to overcome the insulin resistance of type 2 diabetes and lower A1C to goal. (Nathan, *et al.,* 2006)

Both patients and providers often hesitate before beginning insulin therapy, despite its proven efficacy and cost advantage compared to many newer agents. Hypoglycemia and weight gain;

and the patient's perception that insulin therapy is associated with worsening of diabetes are factors contributing to patient hesitancy. An international survey of over 3600 nurses and doctors in 13 countries revealed that clinicians who delay initiating insulin therapy have also delayed initiating oral medication, and that specialists and opinion leaders are less likely to delay starting insulin (Peyrot, *et al.*, 2005).

2. Literature review:

2.1 Clinical pharmacy defined:

Clinical pharmacy is a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention. The practice of clinical pharmacy embraces the philosophy of pharmaceutical care; it blends a caring orientation with specialized therapeutic knowledge, experience, and judgment for the purpose of ensuring optimal patient outcomes. As a discipline, clinical pharmacy also has an obligation to contribute to the generation of new knowledge that advances health and quality of life. (American College of Clinical Pharmacy, 2008)

2.2 Pharmaceutical care:

Pharmaceutical care has been defined by Hepler and Strand in 1990, as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life. These outcomes are (1) cure of disease, (2) elimination or reduction of a patient’s symptomatology, (3) arresting or slowing of a disease process, or (4) preventing a disease or symptomatology” (Hepler and Strand, 1990). The word ‘pharmacist’ is not part of the definition. Pharmaceutical care can, therefore be regarded as achievable through the collaborative work of a team of health professionals, including pharmacists, but also including technicians, doctors and nurses. It also enables pharmaceutical care to be delivered in different methods, in different clinical settings e.g. hospital wards, primary care settings and community pharmacies. The concept of pharmaceutical care is, therefore, a description of what the patient should receive and not what the pharmacist does. It is this model which has been mainly used and adapted to shape the delivery of pharmacy practice and the delivery of pharmaceutical care (Hudson, *et al*., 2007).

A pharmacist has the possibility to provide pharmaceutical care on a full-time basis, and is, therefore, expected to take the primary role as the pharmaceutical care provider. The pharmacist can successfully take on the responsibilities of identifying, resolving and preventing drug-therapy problems (Strand, *et al*., 2004).

2.3 Role of clinical pharmacist in the management of diabetes:

Since 1995, there have been numerous studies of the impact of pharmacists' care on the health of persons with diabetes. A variety of outcomes have been assessed including clinical parameters (e.g., blood glucose, low-density lipoprotein cholesterol, HbA1c, blood pressure), humanistic parameters (health-related quality of life, satisfaction), and costs for care (Guirguis, *et al*., 2003).

Van Veldhuizen-Scott, *et al.* (1995) reported their assessment of a pharmaceutical care model for patients with diabetes. They added a pharmacist intervention (either group-education or individualized education) to existing multidisciplinary diabetes education program. The patients receiving individualized monitoring were contacted twice monthly for 2 months. At the end of the second month, patients in the intervention groups showed significantly lower average weekly blood glucose levels and a lower incidence of hyperglycemic episodes compared with the control group. Questionnaire data for both treatment groups indicated a significant increase in patient understanding of diabetes medications and medications for concomitant illnesses, an increase in knowledge about glucose monitoring, and a positive difference in perceptions and attitudes toward diabetes and communication with the pharmacist (Van Veldhuizen-Scott, *et al.*, 1995).

Jaber, *et al.* (1996) also demonstrated the positive impact of pharmacists providing care in a clinic that served an urban, minority population. Patients with Type 2 diabetes were randomly

assigned to either a pharmacist-based care program (intervention group) or standard medical care (control group). Patients in the intervention group received diabetes education, medication counseling, directions on dietary regulation, exercise, and home blood glucose monitoring, and evaluation and adjustment of their hypoglycemic regimen. Patients in the control group continued to receive standard medical care provided by their physicians. The pharmacists also ordered laboratory results, monitored patients' adherence to the lifestyle changes and drug therapy, and adjusted the medication regimen as necessary. Patients returned to the clinic every 2-4 weeks for 4 months. Thirty-nine patients (17 intervention, 22 control) completed the study. Significant improvement in HbA1c and fasting blood glucose was achieved in the intervention group. No improvement in glycemia was observed in the control subjects. Statistically significant differences in the final HbA1c and fasting blood glucose concentrations were noted between groups (Jaber, *et al.*, 1996).

Pharmacists in Asheville, North Carolina, implemented a diabetes care program for self-insured employers in 1997. On average, patients' HbA1c concentrations were significantly reduced, and their satisfaction with pharmacy services improved significantly during their first 12 months in the program. Over the initial year of the program, participants' mean A1C decreased from 7.9% at initial visit to 7.1%, mean LDL-C decreased from 113.4 mg/dL to 104.5 mg/dL, and mean systolic blood pressure decreased from 136.2 mm Hg to 131.4 mm Hg. During this time, influenza vaccination rate increased from 52% to 77%, the eye examination rate increased from 46% to 82%, and the foot examination rate increased from 38% to 80%. Patient satisfaction with overall diabetes care improved from 57% of responses in the highest range at baseline to 87% at this level after 6 months, and 95.7% of patients reported being very satisfied or satisfied with the

diabetes care provided by their pharmacists. Total mean health care costs per patient were $918 lower than projections for the initial year of enrollment (Garrett and Bluml, 2005).

This results of Ashville project persisted for many patients over a 5-year period; mean A1c decreased at all follow-ups, with more than 50% of patients demonstrating improvements at each time. The number of patients with optimal A1c values (< 7 %) also increased at each follow-up. More than 50% showed improvements in lipid levels at every measurement. (Cranor, *et al*., 2003).

Coast-Senior *et al*. (1998) examined the impact of diabetes care provided by pharmacists in a Veterans Affairs Health Care System (VAHCS) clinic in Pittsburgh. Patients with difficult to control diabetes were referred to the clinic by their primary care providers. The pharmacists provided diabetes education, medication counseling, monitoring, and insulin initiation and adjustments. They followed 23 subjects for an average of 27 weeks. HbA1c, fasting plasma glucose concentrations, and random blood glucose concentrations significantly decreased from baseline by 2.2%, 65 mg/dL, and 82 mg/dL, respectively. Symptomatic hypoglycemia occurred in 35% of patients. None of these episodes needed physician intervention.

In another study Gerber, *et al.* (1998) compared the health-care costs of Kaiser-Permanente members with diabetes who visited either an enhanced-care pharmacy or a traditional pharmacy. The patients who visited the enhanced-care pharmacies were assumed to have received additional counseling and monitoring. Their data indicate that pharmacist consultations provided to patients with diabetes can decrease total health-care costs in a health maintenance organization (Gerber, *et al*., 1998).

Pharmacists in a Veterans Affairs Health Care System (VAHCS) clinic in California also confirmed the positive impact of pharmacists on veterans with diabetes (Gong, *et al*., 1999).

They studied 81 subjects who were assigned to either a traditional primary care model for diabetes or a diabetes disease management clinic (DDMC) in which a pharmacist or nurse provided education, monitoring, and dosage adjustments under protocol. At the follow up, patients referred to the DDMC achieved a significantly greater reduction in HbA1c compared to those patients not enrolled in the clinic (-1.6% vs. -0.4%). Patients who were not enrolled in DDMC failed to achieve a significant decrease in HbA1c from baseline, whereas the follow-up HbA1c values in patients enrolled in the DDMC were significantly lower than baseline (Gong, *et al*., 1999).

Berringer, *et al.* (1999) reported the results of a diabetes monitoring program at two community pharmacies in Virginia. This program was integrated with the dispensing system in which data was collected from patients at the time of each medication refill [point-of-dispensing (POD)].

Eighty two patients were selected to participate in the study, 62 (76%) completed the first 6 months and 52 (63%) completed the entire 12-month follow up period. Patients were instructed on the use of blood glucose meters and they provided their monitoring results to the pharmacists at each visit. Patient charts were reviewed at a later time when pharmacists were free of usual dispensing responsibilities, and the pharmacists provided recommendations to the patient's physician when essential. Average morning blood glucose values decreased from 178.6 mg/dL to 159.3 mg/dL, from baseline to 6 months, respectively. Blood glucose values at baseline and 12 months decreased from 179.0 mg/dL to 149.7 mg/dL, respectively. The authors concluded that point-of-dispensing model offers an effective and efficient mechanism for providing pharmaceutical care for subjects with diabetes (Berringer, *et al.*, 1999).

Davidson, *et al.* (2000) implemented a pharmacist-managed diabetes care service in a free medical clinic that served a poor, minority population. The pharmacist provided diabetes care

according to physician-designed protocols including the initiation/adjustment of therapy, ordering laboratory tests, and limited physical evaluation of patients. Patients in the experimental group (n = 79) received the pharmacist-care program while a control group (n = 73) received standard care at the clinic. Compared with the control group, the initial HbA1c level in the experimental group was significantly higher (8.8 versus 7.9) but fell significantly more (-0.8 - 0.2 versus -0.05 ± 0.3). Also, patients with proteinuria were more likely to be treated with an ACE inhibitor or an ARB if they were in the pharmacist-care group. (Davidson, *et al.*, 2000)

Kelly and Rodgers (2000) evaluated the impact of a pharmacist-managed diabetes service on changes in HbA1c, blood pressure, lipids, and smoking status in diabetic patients in pharmacist-managed diabetes service compared to results of standard medical care provided by physicians in a matched historical control. Patients in the intervention group received dosage adjustments, diabetes self-management training, and periodic assessment of treatment goals by pharmacists. At the end of the study the HbA1c was 7.5% for the intervention group and 8.5% for the historical control group (Kelly and Rodgers, 2000).

Irons, *et al.* (2002) at Texas Tech University conducted a study of diabetes care provided in a physician-supervised, pharmacist-managed primary care clinic. They compared the glycemic control of 87 subjects with diabetes whose drug therapy was managed by a pharmacist to a control group of 85 similar patients whose care was not amplified by a pharmacist. Primary outcomes were differences in fasting blood glucose (FBG) and HbA1c levels between groups. The relative risk (RR) of achieving an A1C of 7% or below was significantly higher in the study cohort (RR 5.19, 95% confidence interval [CI] 2.62-10.26). The frequency of hypoglycemia did not differ between groups. The average number of unscheduled clinic visits related to diabetes was higher in the control group, however. Thus, the pharmacist-managed patients were more

likely to achieve optimal glycemic control and less likely to need unscheduled visits (Irons, *et al.*, 2002).

Clifford and colleagues (2005) proved that a 12-month pharmaceutical care (PC) program in type 2 diabetes reduced glycemia and blood pressure. They recruited 198 community-based patients randomized to PC or usual care. PC patients had face-to-face goal-directed medication and lifestyle counseling at baseline and at 6 and 12 months plus 6-weekly telephone assessments and provision of other educational material. The main outcome measure was change in HbA1c. A diabetes-specific risk engine was used to estimate changes in 10-year coronary heart disease (CHD) and stroke risk in patients without a history of cardiovascular disease. Mean reductions were greater in PC case subjects than control subjects for HbA1c (-0.5% [95% CI -0.7 to -0.3] vs. 0 [-0.2 to 0.2]). The median 10-year estimated risk of a first CHD event decreased in the PC case subjects but not the control group (Clifford, *et al.*, 2005).

Rothman, *et al.* (2005) also conducted a study to assess the efficacy of a pharmacist-led, primary care–based, disease management program to improve cardiovascular risk factors and HbA1c levels in vulnerable patients with poorly controlled diabetes. Intervention patients received intensive management from clinical pharmacists, as well as from a diabetes care coordinator who provided diabetes education, applied algorithms for managing glucose control and decreasing cardiovascular risk factors, and addressed barriers to care. The intervention group had significantly greater improvement than did the control group for systolic blood pressure (-9 mm Hg; 95% confidence interval [CI]: -16 to -3 mm Hg) and HbA1c level (-0.8%; 95% CI: -1.7% to 0%) (Rothman, *et al.,* 2005).

In a study conducted by Altavela, *et al.* (2008) the main purpose was to determine whether the recommendations of a clinical pharmacist embedded in a primary care practice, which had not

previously received services from clinical pharmacists, would decrease the medical costs of capitated patients. There were 127 and 216 adult patients in the intervention and comparison groups, respectively. The primary outcome, change in mean medical cost, did not differ significantly between the groups ($P = 0.711$), but intervention group patients were more likely than comparison group patients to have the following issues addressed: medication non-adherence (85.7% vs. 40.0%, respectively; $P = 0.032$), untreated indication (72.6% vs. 11.5%, $P < 0.001$), suboptimal medication choice (60.0% vs. 5.9%, $P < 0.001$) and cost-ineffective drug therapies (72.1% vs. 6.5%, $P < 0.001$) (Altavela, *et al*., 2008).

Most of these studies have involved small samples (<50 subjects), were nonrandomized, targeted particular patient groups such as insulin-treated type 2 subjects, older patients (> 55 years of age), and those with a relatively high HbA1C at > 8% or > 9.0%, and/or did not recruit a contemporary control group, while others did not report glycemic outcomes or adjust for baseline differences in glycemic variables between intervention and control.

This indicated the need for a larger prospective, randomized, controlled study that includes a sufficient number of subjects, with an intervention that combines pharmacotherapy changes and patient education. Outcomes should optimally include changes in glycemic and metabolic outcomes, patient adherence, and quality of life.

3. Aims and objectives:

The aim of this study is to investigate the effect of comprehensive, pharmacist-delivered, patient-focused intervention to improve the quality of care for patients with diabetes measured by a range of clinical outcomes.

Specific objectives:

- To determine the prevalence and nature of treatment related issues in outpatients with diabetes.
- To assess if clinical pharmacist is able to improve evidence-based pharmacotherapy through identifying, resolving, and preventing treatment related issues.
- To assess the impact of clinical pharmacist on metabolic control of DM and cardiovascular risk factors.
- To assess the impact of clinical pharmacist on adherence to medications and life style changes.
- To assess the impact of clinical pharmacist on knowledge about DM and its treatment.

4. Method

4.1 Study design:

This study is a prospective, randomized controlled trial.

4.2 Clinical setting:

The study was started after obtaining approval from the Local Research Ethics Committee of University of Jordan Hospital. Data were collected at the Endocrine outpatient clinics in the hospital. Patients' recruitment started in October 2010 until December 2010, and follow up took place from January 2011 until April 2011.

The Endocrine clinic's team consists of two consultants, three fellows, one senior resident, one junior resident, a nurse responsible for patient education, and a dietitian.

4.3 Sample size:

The average number of patients per day in the Endocrine clinic is about 60; about 30 of them are diabetics. Among them, about 20 are type 2 diabetics.

The first 4 type 2 diabetic patients that enter the clinic where the clinical pharmacist is sitting were approached and asked to participate in the study.

Out of 128 diabetic patients who were approached, 4 refused to participate in the study due to time constrains. Thus, 124 patients were recruited.

4.4 Study subjects:

Inclusion criteria:

- age more than 18 years,
- confirmed diagnosis of diabetes mellitus by a hospital consultant,
- receiving hypoglycemic agents,
- patient provided written informed consent to their participation in the research.

Exclusion criteria:

- gestational diabetes
- diabetes diagnosed since less than 6 months.

Two patients were excluded from the study because they were identified to have major treatment related issues, but, according to the randomization, they were assigned to control group, and leaving them without pharmaceutical care was unethical.

4.5 Baseline data collection:

After recruitment patients were randomly assigned to either the intervention or the control group.

Patients were then interviewed by the Clinical Pharmacist to obtain details on:

- demographics,

- family history of diabetes and cardiovascular disease,

- medications used,

- frequency of self-monitoring of blood glucose at home,

- knowledge about diabetes mellitus and medications,

- beliefs about diabetes treatment and treatment goals,

- adherence to medications,

- adherence to life style advice

Baseline data for body weight, BMI, HbA1c, fasting and random blood glucose, blood pressure, LDL, HDL, TG, total cholesterol, and serum creatinine were also recorded.

Patients' medical files were also reviewed for identification of treatment-related issues.

Social desirability was minimized by allowing the patients to fill the questionnaires themselves after being clarified by the pharmacist, and returning them to the pharmacist without being shown to the clinic's physicians.

4.6 Identification of treatment related problems:

Patients' diabetes treatment was assessed versus American Diabetes Association, Standards of Medical Care in Diabetes (2010) recommendations to identify any treatment-related problems (TRPs). Treatment of other illnesses in the patients was also checked against the latest clinical practice guideline recommendations.

Dosing regimens and drug-drug interactions were checked using the latest version of Lexi-Comp's drug information (Lacy *et al*., 2010) and drug interaction software (Lexi-Interact^{TM} , 2010)

4.7 Classification of treatment related issues:

We used AbuRuz *et al.* (2006) classification of treatment related issues which divides them into 6 main categories:

1- Indication
2- Efficacy
3- Safety
4- Knowledge
5- Adherence
6- Miscellaneous

Each of the above main categories is divided into subcategories as follows:

Table 2: Classification of treatment related problems (AbuRuz *et al.,* 2006)

Type Of Problem	Assessment
1. Unnecessary drug therapy	a) Drug use without an indication b) Addiction or recreational drug use c) The patient treatment should be stepped down (at this stage the patient needs non pharmacological

	therapy alone or he doesn't need combination therapy because of improvement in condition or because of guideline recommendations) d) Duplication (two drugs from the same pharmacological class with no clinical evidence approving such combination) e) Treating avoidable adverse reaction
2. Untreated condition	a) Untreated conditions that require drug therapy
3. Efficacy drug related problems	a) More effective drug is available/ recommended b) The patient requires additional/ combination therapy or stepping up because of actual or potential therapy failure or because of guidelines recommendation c) Efficacy dosage regimen issues d) Efficacy interactions issues
4.Safety drug related problems	a) A current drug is contraindicated/unsafe for patient condition and should be stopped, monitored. b) Safer drug therapy is recommended. c) The patient is at high risk for developing ADR and

	needs monitoring or prophylaxis d) Allergic reaction or undesirable effects: Are there symptoms or medical problems that may be drug induced? e) Safety dosage regimen issues f) Safety interactions issues
5. Inappropriate knowledge	a) The patient is not instructed or does not understand important information regarding his medications (the purpose of his or her medication(s), how much, how and when to take it, what to avoid, how to prevent side effect and how to monitor his treatment) b) The patient is not instructed or does not understand non-pharmacological therapy or self care advice (avoidance of risk factors, smoking, alcohol, diet, exercise, etc.)
6. Inappropriate adherence	a) A problem in patients' adherence to medications (forget, skip, can not afford, Cannot swallow/administer drug etc) b) Drug product not available. c) A problem in patients' adherence to self care

	activities or non pharmacological therapy d) A problem in patients' adherence appointment e) A problem in patients' adherence to doing periodic lab results.
7.Miscellaneous	a) A need for additional or more frequent monitoring b) A need for additional diagnostic test c) A need for consultation

4.8 Intervention group:

During the first visit, the clinical pharmacist provided the following components of pharmaceutical care:

1- Educated about the definition, nature and symptoms of diabetes mellitus
2- Educated about goals of treatment and medications used to treat diabetes
3- Educated about lifestyle modifications (diet, exercise…. etc.) that are a part of diabetes treatment.
4- Encouraged to self-monitor blood glucose several times a day.
5- Encouraged to adhere to both pharmacological and non-pharmacological treatments of diabetes.

6- Educated about other chronic diseases that they had, that may or may not affect diabetes.

7- Educated about symptoms of hypoglycemia and importance of quick treatment

4.9 Communicating treatment related issues:

After collecting essential data, treatment related issues identified were filled in clinical pharmacist's consult note forms and discussed with the physician.

Modifications of treatment that were agreed upon were applied to the patients' treatment.

4.10 Control group

Patients in the control group did not receive any advice by the clinical pharmacist; however they received their normal care by other members of the medical team.

Normal care consists of modification of patients by the physicians and referral to the clinic's dietitian when necessary.

4.11 Follow up

Both the intervention and the control groups were asked to return to the hospital for a follow-up visit three months after the first interview to allow assessment.

At the follow up visit, both the control and the intervention groups had the following assessment:

- objective data: HbA1c value, fasting and random blood glucose, blood pressure, LDL, HDL, TG, and total cholesterol;

- patent's knowledge about diabetes nature and complications;

- patient's knowledge about pharmacological and non-pharmacological treatments of diabetes;

- patient's knowledge about medications, their proper use and side effects;

- adherence to pharmacological and non-pharmacological interventions.

Outcomes:

- HbA1c
- Fasting blood glucose (Random blood glucose was taken if fasting was not available)
- Blood pressure
- Lipid profile
- Patient's knowledge about diabetes nature and complications
- Patient's knowledge about pharmacological and non-pharmacological treatments of diabetes
- Patient's knowledge about medications and their proper use and side effects
- Adherence to pharmacological and non-pharmacological interventions.

4.11 Data analysis:

Data was analyzed using SPSS software version 16.0. Suitable types of tests were used according to the function required: for continued variables, paired t-test to compare follow-up values with baseline values or independent samples t-test to compare data from two different groups. For categorical variables, Chi-square or McNemar tests were used. $P<0.05$ was considered to be statistically significant.

4.12 Instruments:

Knowledge about drug therapy questionnaire (Appendix 2)

Patients' knowledge about medications was assessed by asking the patients about seven items related to their medications, including medication dose, frequency of use, duration of use, any special alert, knowledge of the drug, knowledge about efficacy, and knowledge about safety of each drug. For each item, patient's knowledge was recorded as either yes (enough knowledge) or no (not enough knowledge). The higher was the score out of 7, the better was considered the patient's knowledge about drug therapy.

The patient was considered to have a problem with their knowledge regarding drug therapy if they scored 6 or less in the total knowledge score. The questionnaire was obtained from the Pharmaceutical Care Manual (AbuRuz *et al*., 2007a).

Self reported medication adherence questionnaire (Appendix 3)

Adherence to medications was assessed through patient interview. The questionnaire used was developed and validated by AbuRuz *et al*. (2009) who based their work on a scale developed by

Morisky *et al*. (1986). The questionnaire is composed of five items asking the patient how often during the last month they forgot to take their medications, skipped their medications, stopped their medications when they felt better, stopped their medications when they felt worse or stopped their medications when they experienced side effects.

Subjects were asked to report: “never”, “rarely”, “sometimes”, “often”, or “always” when they were asked if they had ever experienced the different aspects of non adherence.

Self reported adherence to self care activities questionnaire (Appendix 4)

The SDSCA (Summary of Diabetes Self-Care Activities Measure) is a brief self-report questionnaire of diabetes self-management that includes items assessing the following aspects of the diabetes regimen: general diet, specific diet, exercise, blood-glucose testing, foot care, and smoking. The SDSCA is probably the most widely used self-report instrument for measuring diabetes self-management in adults. The questionnaire is based on the summary of diabetes self-care activities questionnaire (Toobert *et al*., 2000) and was translated into Arabic and validated by AbuRuz *et al*. (2007b). It has good internal consistency, concurrent validity and test–retest validity. The instrument asks the patients to recall their self-care behavior during the previous seven days. It contains questions related to diet (4 questions), exercise (2 questions), blood glucose monitoring (2 questions), foot care (2 questions) and smoking (1 question). Since diabetes self-care is multidimensional, we assessed each of its components separately rather than combined scores across components (Johnson, 1992).

5. Results:

5.1 Description of the study sample

During the study period, the endocrine and diabetes clinic served about 20 patients with type 2 DM every day. Due to time constraints, an average of 4 patients was randomly chosen to participate in the study.

Patients who agreed to participate were interviewed, and all other required data were collected according to the procedure detailed in the methodology.

Demographic characteristics:

The demographic details of the patients included in the study are shown in Table 3. Mean age of the participants was 58.27 years and 47.5 % were males. Most of the participants were married (85.5 %) and only 8.9% of them were not educated. The majority of patients were either overweight (33.1%) or obese (56.5%), their mean BMI (31.5 Kg\m^2) falling in the obese category

Table 3: Demographic characteristics of the study sample (N=124)

Parameter	Total, N (%)	Intervention, N (%)	Control, N (%)
Number	124	61 (49.2)	63 (50.8)
Age, years,			
mean (SD)	58.27 (11.45)	59.95 (12.053)	56.65 (10.679)
[Age Range]	[28-86]	[28-84]	[30-86]
Gender			
Male	59 (47.6)	32 (52.4)	27 (42.8)
Female	65 (52.4)	29 (47.5)	36 (57.1)
Marital status			
Married	106 (85.5)	51 (83.6)	55 (87.3)
Single	6 (4.8)	3 (4.9)	3 (4.7)
Widowed	11 (8.9)	6 (9.8)	5 (7.9)
Divorced	1 (0.8)	1 (1.6)	0 (0)
Education			
Illiterate	11 (8.9)	7 (11.4)	4 (6.3)
Primary	24 (19.4)	11 (18.0)	13 (20.6)
Secondary	54 (43.5)	26 (42.6)	28 (44.4)
High education	35 (28.2)	17 (27.8)	18 (28.5)
Weight, Kg			
mean (SD)	85.3 (15.71)	84.67(15.34)	85.89(16.16)
BMI, Mean (SD)	31.55 (5.65)	30.90 (5.80)	32.18 (5.48)

BMI categories (N=123)			
Underweight	0 (0)	0 (0)	0 (0)
Normal weight	12 (9.7)	7 (11.5)	5 (7.9)
Overweight	41 (33.1)	24 (39.3)	17 (27)
Obese	70 (56.5)	29 (47.5)	41 (65.1)

- Values are expressed as number (percentage) unless otherwise indicated

Clinical characteristics

Clinical characteristics of the study participants are shown in Table 4. More than half of the patients enrolled in the study were found to have retinopathy, and more than half of them had neuropathy.

The average HbA1c at the baseline was 8.16 %, FBS was 156 mg/dL, blood pressure was 129/75 mm Hg, and LDL was 99.2 mg/dL.

The percentage of patients who had hypertension was 82 %, dyslipidemia was 75.8 %, IHD was 20.9 %, and heart failure was 5.6 %.

The most frequent glucose-lowering agent among study sample was metformin, followed by insulin with a frequency of 87.9 %, and 47.5 % respectively (Table 5).

Table 4: Clinical characteristics of the study sample at baseline

Parameter	Total, N (%)	Intervention, N (%)	Control, N (%)	*P* *
DM Duration, years (SD)	9.66 (7.417)	11.57 (7.749)	7.80 (6.629)	
HbA1c, % mean (SD)	8.168 (1.8075)	8.751 (1.8998)	7.603 (1.526)	.000
FBS, mg/dL, mean (SD)	157.82 (64.79)	178.36 (71.54)	138.61 (51.29)	.003
Presence of retinopathy	66 (53.2)	35 (57)	31 (49.2)	
Presence of nephropathy	14 (11.3)	9 (14.7)	5 (7.9)	
Presence of neuropathy	64 (51.6)	35 (57.3)	29 (46.0)	
Controlled BP	39 (31.4)	20 (32.7)	19 (30.1)	
Controlled lipid profile	11 (11.22)	4 (8.7)	7 (13.46)	
Hypoglycemic episodes	27 (21.77)	13 (21.3)	14 (22.22)	
Smoking	25 (20.16)	12 (19.67)	13 (20.63)	

- Values are expressed as number (percentage) unless otherwise indicated

* *P* value by independent sample T-test

Table 5 shows the frequency of use of antihyperglycemic, antihypertensive, lipid-lowering, diuretic, and antiplatelet medications.

Table 5: Frequency of use of antihyperglycemic, antihypertensive, lipid lowering, diuretic, and antiplatelet medications at baseline.

Class	N (%)*	Medication name	Total, N (%)**	Intervention, N (%)***	Control, N (%)***
Insulin	75 (47.5)	Mixtard	38 (50.66)	20 (32.79)	18 (28.57)
		Lantus	21 (28)	13 (21.13)	8 (12.7)
		Actrapid	16 (21.33)	11 (18.03)	5 (7.93)
Biguanides	109 (87.9)	Metformin	109 (100)	52 (85.25)	57 (90.47)
Sulfonylureas	49 (39.5)	Glimperide	33 (67.34)	16 (26.23)	17 (26.98)
		Glibenclamide	9 (18.36)	5 (8.2)	4 (6.45)
		Gliclazide	7 (14.2)	3 (4.91)	4 (6.35)
DPP-IV inhibitors	1 (0.8)	Sitagliptin	1 (100)	0 (0)	1 (1.58)
ACEIs	55 (44.3)	Enalapril	37 (67.27)	17 (27.87)	20 (31.74)
		Lisinopril	5 (9.09)	2 (3.28)	3 (4.76)
		Captopril	1 (1.81)	1 (1.64)	0 (0)
		Ramipril	12 (21.81)	6 (9.84)	6 (9.52)

Beta blockers	51 (41.12)	Atenolol	21 (41.17)	13 (21.31)	8 (12.7)
		Metoprolol	1 (1.96)	1 (1.64)	0 (0)
		Bisoprolol	24 (47.05)	10 (16.4)	14 (22.22)
		Carvedilol	5 (9.8)	5 (8.2)	0 (0)
CCBs	24 (19.4)	Amlodipine	21 (87.5)	12 (19.6)	9 (14.28)
		Nifedipine	2 (8.33)	1 (1.64)	1 (1.58)
		Felodipine	1 (4.16)	1 (1.64)	0 (0)
ARBs	34 (27.4)	Candesartan	21 (61.7)	11 (18.03)	10 (15.87)
		Valsartan	9 (26.47)	4 (6.55)	5 (7.93)
		Irbesartan	4 (11.7)	3 (4.91)	1 (1.58)
Diuretics	55 (44.3)	HCTZ	13 (23.63)	7 (11.57)	6 (9.52)
		Indapamide	22 (40)	9 (14.75)	13 (20.63)
		Furosemide	20 (36.36)	12 (19.67)	8 (12.7)
Lipid-lowering agents	99 (79.8)	Atorvastatin	42 (42.42)	19 (31.14)	23 (36.5)
		Simvastatin	43 (43.43)	17 (27.87)	26 (41.26)
		Rosuvastatin	5 (5.05)	3 (4.91)	2 (3.17)
		Fluvastatin	1 (1.01)	0 (0)	1 (1.58)
		Gemfibrozil	8 (8.08)	3 (4.91)	5 (7.93)
Antiplatelets	106 (85.4)	Aspirin	102	50 (81.97)	52 (82.53

			(96.22)		
		Clopidogrel	4 (3.77)	3 (4.91)	1 (1.58)

* Percent within total

** Percent within class

*** Percent within patient group

DPP-IV: Dipeptidyl peptidase-4 inhibitor

CCBs: Calcium channel blockers

ACEIs: Angiotensin converting enzyme inhibitors

ARBs: Angiotensin receptor blockers

5.2 Baseline data

5.2.1 Baseline self reported adherence to self care activities

Table 6 shows the means for the various self-care activities performed by the patients at the beginning of the study.

Table 6: Baseline self reported adherence to self care activities

Self care aspect	Total sample, mean (SD)	Intervention, mean (SD)	Control , mean (SD)	*P**
Number of days‡ with diabetic diet in last week	3.24 (2.683)	3.25 (2.54)	3.22 (2.82)	0.955
Number of days‡ with diabetic diet in the last month as an average	3.07 (2.612)	3.05 (2.45)	3.10 (2.76)	0.908
***Diet* (days/week)**	3.1789 (2.63576)	3.2000 (2.49780)	3.1587 (2.78073)	0.931
Number of days‡ with five or more servings of fruit and vegetables	2.85 (2.131)	2.53 (1.81)	3.14 (2.36)	0.113
Number of days‡	2.76 (1.606)	2.62 (1.55)	2.89 (1.65)	0.349

with high fat diet				
***Specific diet* (days/week)**	3.5447(1.20961)	3.4583 (1.11724)	3.6270 (1.29505)	0.440
Number of days‡ with at least 30 minutes exercise	1.95 (2.734)	1.87 (2.72)	2.03 (2.76)	0.739
Number of days‡ with special kind of sport (swimming, running..)	.14 (.926)	.12 (0.904)	.16 (0.95)	0.802
***Exercise* (days/week)**	1.0447(1.56028)	0.9917 (1.53626)	1.0952 (1.59348)	0.714
Number of days‡ with glucose monitoring	2.06 (2.546)	2.27 (2.58)	1.86 (2.51)	0.375
Number of days‡ with glucose monitoring as directed by a physician as an average	.37 (1.444)	.23 (1.26)	.49 (1.59)	0.323
***Glucose monitoring* (days/week)**	1.2114 (1.68407)	1.2500 (1.62215)	1.1746 (1.75324)	0.805

Number of days‡ with foot check	5.59 (2.667)	5.90 (2.41)	5.29 (2.87)	0.201
Number of days‡ with shoe check	3.93 (3.323)	4.53 (3.22)	3.37 (3.33)	0.051
***Foot care* (days/week)**	4.7602 (2.65838)	5.2167 (2.51161)	4.3254 (2.74032)	0.062
Daily cigarettes	4.13 (12.209)	4.57 (14.56)	3.71 (9.54)	0.7

‡ per week

* *P* value by independent sample T-test

The table shows that there is a defect in patients' adherence to self care activities. Patients tend to adhere to healthy diet in about 3.5 days per week only, and eat five servings of fruits or vegetables in less than three days a week. With regard to exercise, patients exercise for more than 30 minutes a day in less than 2 days per week as an average. On the other hand, patients perform SMBG in about 2 days per week.

5.2.2 Baseline knowledge about medications

The average score of the subjects' knowledge about medications in the study sample is shown in Table 7.

Table 7: Baseline knowledge about medications

	Intervention, mean (SD)	Control, mean (SD)	*P**
Score	3.5033 (1.95380)	3.8710 (2.06988)	0.313
* *P* value by independent sample T-test			

Table 8 shows the number of patients in the intervention and control groups that have appropriate knowledge about all aspects of medications (those who were given a score of 7).

Table 8: Number of patients with appropriate knowledge about medications in the intervention and control groups at baseline

	Total sample, N (%)	Intervention, N (%)	Control, N (%)
Patients with appropriate knowledge about medications	16 (12.9)	6 (9.8)	10 (15.9)
P (Chi square test): 0.232			

5.2.3 Baseline self-reported adherence to medications

Table 9 shows the number of patients in the intervention and control groups that are adherent to their medications, and did not answer any of the questions related to adherence to medications with “sometimes”, “often”, or “always”.

Table 9: Number of patients who are adherent to medications

	Total sample, N (%)	Intervention, N (%)	Control, N (%)
Number of patients that are adherent to medications (%)	96 (77.4)	48 (78)	48 (76)
P (Chi square test): 0.739			

The main reported under-adherence problems in the study sample were “stop to take medications from time to time”, and “stop if they experience side effects”, as measured by the number of patients who answered with “sometimes”, “often”, or “always”.

5.2.4 Baseline education level about non-pharmacological therapy

Table 10 shows the number of patients who were educated about non-pharmacological therapy for DM. The worst awareness among the study sample was regarding the importance of proper foot care.

Table 10: Baseline education level about non-pharmacological therapy of DM

Patient Education Aspect	Total sample, N (%)	Intervention, N (%)	Control, N (%)	*P* *
Number of patients who were educated about DM	90 (72.5)	45 (73)	45 (71)	0.770
Number of patients who were educated about medications	74 (59.6)	33 (54)	41 (65)	0.213
Number of patients who were educated about proper diet	56 (45.1)	24 (39)	32 (50)	0.200
Number of patients who were educated about the importance of exercise	34 (27.4)	12 (20)	22 (34)	0.057
Number of patients who were educated about SMBG	21 (16.9)	8 (13)	13 (20)	0.264
Number of patients who were educated about proper foot care	17 (13.7)	8 (13)	9 (14)	0.850
Number of patients who were educated about smoking	23 (18.5)	9 (14)	14 (22)	0.285

* *P* value by Chi square test

5.3 Treatment related problems at baseline

The total number of identified treatment related problems was 489 [mean 3.94 per patient].

Table 11 and Figure 2 show the distribution of treatment related problems according to their type. Efficacy treatment related problems were the most frequent (40%) in the population studied.

Table 11: Treatment related problems

Treatment related problem category N (%)*	**Treatment related problem**	N (%)**
Unnecessary drug therapy : 10 (2.04)	a) Drug use without an indication	6 (60)
	b) Addiction or recreational drug use	0 (0)
	c) The patient treatment should be stepped down (at this stage the patient needs non pharmacological therapy alone or he doesn't need combination therapy because of improvement in condition or because of guideline recommendations	4 (40)
	d) Duplication (two drugs	0 (0)

	from the same pharmacological class with no clinical evidence approving such combination)	
	e) Treating avoidable adverse reaction	0 (0)
Untreated conditions :23 (4.7)	a) Untreated conditions that require drug therapy	23 (100)
Efficacy drug related problems: 196 (40)	a) More effective drug is available/ recommended	45 (23.5)
	b) The patient requires additional/ combination therapy or stepping up because of actual or potential therapy failure or because of guidelines recommendation	140 (71)
	c) Efficacy dosage regimen issues	11 (5.6)
	d) Efficacy interactions issues	
Safety drug related problems: 32 (6.5)	a) A current drug is contraindicated/unsafe for	9 (28.1)

	patient condition and should be stopped, monitored.	
	b) Safer drug therapy is recommended	2 6.2)
	c) The patient is at high risk for developing ADR and needs monitoring or prophylaxis	1 (3.1)
	d) Allergic reaction or an undesirable effects	1 (3.1)
	e) Safety dosage regimen issues	19 (59)
	f) Safety interactions issues	0 (0)
Inappropriate knowledge: 100 (20.4)	a) The patient is not instructed or does not understand important information regarding his medications (the purpose of his or her medication(s), how much, how and when to take it, what to avoid, how to prevent side effect and how to monitor his treatment)	45 (45)

	b) The patient is not instructed or does not understand non-pharmacological therapy or self care advice (avoidance of risk factors, smoking, alcohol, diet, exercise, etc.)	55 (55)
Inappropriate adherence: 104 (21.26)	a) A problem in patients' adherence to medications (forget, skip, can not afford, Cannot swallow/administer drug etc)	39 (38)
	b) A problem in patients' adherence to self care activities or non pharmacological therapy	65 (62)
Miscellaneous: 25 (5.11)	a) A need for additional or more frequent monitoring	23 (92)
	b) A need for additional diagnostic test	2 (8)
Total		489

* Percent within total number of TRPs

** Percent within class of TRPs

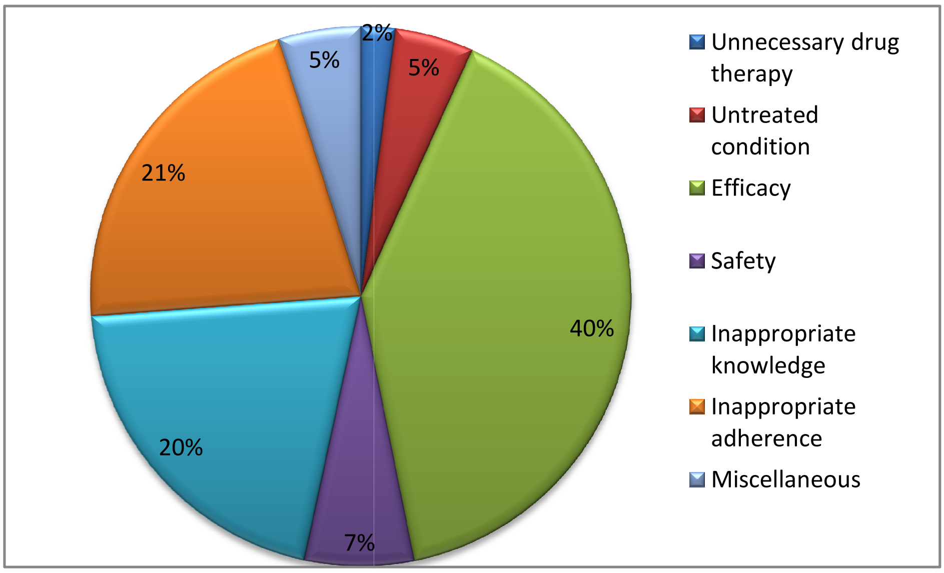


Figure 2: Distribution of treatment related problems.

Note: Total number of treatment related problems = 489.

Each identified treatment related problem was classified into several categories according to its occurrence (actual or potential), its relation to diabetes and to other diseases (Table 12).

Table 12: Types of treatment related problems according to occurrence, relationship to diabetes and other diseases.

	Type of TRP	Number (%)*
Occurrence	Actual	475 (97.1)
	Potential	14 (2.86)
Relation to DM	Related to DM	331 (67.68)
	Not related to DM	158 (32.31)
Related to other diseases	Hypertension	92 (48.9)
	Heart failure	9 (4.78)
	Dyslipidemia	71 (37.76)
	Microablbuminuria	16 (8.51)
* percent of total TRPs		

5.4 Medications related to treatment related problems

Table 13 shows drugs most frequently related to treatment related problems in the study sample.

Mixtard insulin was related to the highest number of treatment related problems.

Table 13: Baseline distribution of TRPs according to medications

Drug class, N (%) *	**Drug, N (%)****	**Treatment related problems, N (%)*****
Insulin: 63 (26.5)	Mixtard: 34 (54)	More effective drug is available/ recommended : 15 (44.11) The patient requires additional/ combination therapy or stepping up: 7 (20.6) Efficacy dosage regimen issues: 3 (8.8) The patient is at high risk for developing ADR and needs monitoring or prophylaxis: 1 (2.9) Safety dosage regimen issues: 8 (23.5)
	Lantus: 18 (28.5)	More effective drug is available/ recommended : 1 (5.55) The patient requires additional/ combination therapy or stepping up:

		17 (94.45)
	Actrapid: 11 (17.4)	The patient treatment should be stepped down : 1 (9.1) The patient requires additional/ combination therapy or stepping up: 10 (90.9)
Biguanides: 15 (6.3)	Metformin: 15 (100)	The patient requires additional/ combination therapy or stepping up: 12 A current drug is contraindicated/unsafe for patient condition and should be stopped, monitored: 3
Sulfonylureas: 21 (8.8)	Glimperide: 16 (76.2)	Drug use without an indication: 1 (6.25) More effective drug is available/ recommended : 5 (23.8) The patient requires additional/ combination therapy or stepping up: 7 (43.75) Efficacy dosage regimen issues: 1 (6.25) Safer drug therapy is recommended:

		1 (6.25) Safety dosage regimen issues: 1 (6.25)
	Glibenclamide: 4 (19)	More effective drug is available/ recommended : 2 (50) The patient requires additional/ combination therapy or stepping up: 2 (50)
	Gliclazide:1 (4.8)	The patient requires additional/ combination therapy or stepping up: 1 (100)
DPP-IV inhibitors: 1 (0.4)	Sitagliptin: 1 (100)	The patient requires additional/ combination therapy or stepping up: 1 (100)
ACEI: 21 (8.8)	Enalapril: 11 (52.4)	Untreated conditions that require drug therapy: 3 (27.3) More effective drug is available/ recommended : 2 (18.2) The patient requires additional/ combination therapy or stepping up: 6 (54.5)
	Ramipril: 7 (33.3)	More effective drug is available/

		recommended : 1 (14.3) The patient requires additional/ combination therapy or stepping up: 6(85.7)
	Lisinopril: 3 (14.3)	The patient requires additional/ combination therapy or stepping up: 2 (66.6) Safety dosage regimen issues: 1 (33.3)
ARBs: 10 (4.2)	Candesartan: 6 (60)	The patient requires additional/ combination therapy or stepping up: 6 (100)
	Valsartan: 4 (40)	The patient requires additional/ combination therapy or stepping up: 1 (25) Efficacy dosage regimen issues: 2 (50) Safety dosage regimen issues: 1 (25)
CCBs: 11 (4.6)	Felodipine: 2 (18.2)	Efficacy dosage regimen issues: 1 (50) A current drug is contraindicated/unsafe for patient condition and should be stopped,

		monitored: 1 (50)
	Amlodipine: 9 (81.8)	More effective drug is available/ recommended : 3 (33.3) A current drug is contraindicated/unsafe for patient condition and should be stopped, monitored: 1 (11.1) Safety dosage regimen issues: 4 (44.4) Drug use without an indication: 1 (11.1)
Beta blockers: 25 (10.5)	Atenolol: 11 (44)	More effective drug is available/ recommended : 4 (36.3) The patient requires additional/ combination therapy or stepping up: 4 (36.3) A current drug is contraindicated/unsafe for patient condition and should be stopped, monitored: 2 (18.2) Allergic reaction or undesirable effects: Are there symptoms or medical problems that may be drug

		induced?: 1 (9.1)
	Bisoprolol: 11 (44)	More effective drug is available/ recommended : 3 (27.2) The patient requires additional/ combination therapy or stepping up: 1 (9.1) Efficacy dosage regimen issues: 3 (27.2) Safety dosage regimen issues: 4 (36.3)
	Carvedilol: 3 (12)	The patient requires additional/ combination therapy or stepping up: 3 (100)
Diuretics: 21	HCTZ: 8 (38.1)	More effective drug is available/ recommended : 1 (12.5) The patient requires additional/ combination therapy or stepping up: 7 (87.5)
	Furosemide: 7 (33.33)	More effective drug is available/ recommended : 4 (57.1) Efficacy dosage regimen issues: 1 (14.2) Drug use without an indication: 1

		(14.2) The patient treatment should be stepped down : 1 (14.2)
	Indapamide: 5 (23.8)	Drug use without an indication: 1 (20) The patient requires additional/ combination therapy or stepping up: 4 (80)
	Spironolactone: 1 (4.7)	Drug use without an indication: 1 (100)
Statins: 29 (12.2)	Rosuvastatin: 2 (6.9)	More effective drug is available/ recommended : 1 (50) The patient requires additional/ combination therapy or stepping up: 1 (50)
	Simvastatin: 11 (38)	Untreated conditions that require drug therapy: 1 (9.1) More effective drug is available/ recommended : 1 (9.1) The patient requires additional/ combination therapy or stepping up: 9 (81.8)
	Atorvastatin: 16 (55.1)	Untreated conditions that require

		drug therapy: 1 (6.25) More effective drug is available/ recommended :2 (12.5) The patient requires additional/ combination therapy or stepping up: 11 (68.75) A current drug is contraindicated/unsafe for patient condition and should be stopped, monitored: 1 (6.25) Safer drug therapy is recommended: 1 (6.25)
Fibrates: 10 (4.2)	Gemfibrozil: 10 (100)	The patient requires additional/ combination therapy or stepping up: 10 (100)
Antiplatelets: 10 (4.2)	Aspirin: 10 (100)	Untreated conditions that require drug therapy: 6 (60) The patient requires additional/ combination therapy or stepping up: 3 (30) A current drug is contraindicated/unsafe for patient condition and should be stopped,

		monitored: 1 (10)

* Percent within the total number of TRPs
** Percent within the TRPs for the medication class

5.5 Type of interventions required for solving treatment related problems

Table 14 shows the type of interventions required for solving the treatment related problems. The most frequently needed intervention was improving adherence of the patient.

Table 14: Type of interventions required for solving the treatment related problems

Intervention type	N (%)
Start new drug	73 (15.1)
Change drug	54 (11.1)
Increase dose	92 (18.9)
Decrease dose	4 (0.8)
Change frequency	24 (4.9)
Monitor	24 (4.9)
Stop drug	10 (2.1)
Improve adherence	104 (21.25)
Improve knowledge	100 (20.4)

5.6 Physician acceptance of clinical pharmacist interventions and result of the interventions

All identified treatment related problems in the intervention group were communicated to the clinic's doctors. Implementation rate for the communicated interventions was more than 95 percent. Table 15 shows the action of the doctors in response to these interventions.

Table 15: Physician acceptance of clinical pharmacist recommendations

Parameter	Total sample, N (%)	Intervention group, N (%)	Control group, (%)
Number of recommendation	489	259 (52.9)*	230 (47.1)
Number of submitted recommendations	163	163 ** (62.9)	0
Number of accepted recommendations		154 (94.4) ***	NA
Number of implemented recommendations		147 (95.4) ****	NA
Number of TRPs corrected by physician without pharmacist intervention		NA	2
* Percent within total TRPs			

** The rest of recommendations were on patient level

*** Percentage within submitted

**** Percentage within accepted

5.7 Follow up data

One hundred and eight patients returned to the clinic for their three- month follow up visit. The rest of the patients were contacted by phone, and they were not able to come to the clinic due to various reasons such as inability to move, being out of country, and loss of insurance coverage.

5.7.1 Weight

Table 16 and figure 3 show the change in mean weight of both the intervention and the control groups.

There has been a decrease in the mean weight of the intervention and an increase in the mean weight of the control, but the difference in the weight change between groups was not statistically significant.

Table 16: Changes in patients' weight at follow up visit

	Baseline weight, kg, mean (SD)	Follow up weight, kg, mean (SD)	Weight change, kg, mean (SD)	*P** within the same group
Intervention	86.11 (16.22)	85.65 (16.61)	- 0.45 (4.22)	0.451
Control	85.42 (15.95)	85.75 (16.09)	0.32 (1.79)	0.178
Independent sample T-test: *P*=0.232 * *P* value by paired sample T-test				

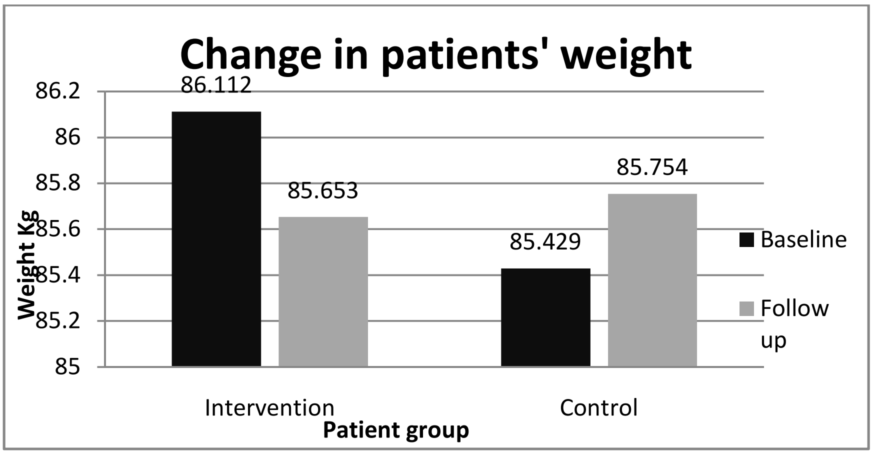


Figure 3: Changes in patients' weight

5.7.2 Body mass index

Table 17 shows the changes in BMI for the intervention and control groups at baseline and follow up. Trends in the BMI changes were similar to the body weight, but the difference between the intervention and control groups did not reach statistically significant level.

Table 17: Changes in BMI for intervention and control groups at follow up visit

	Baseline Mean BMI, mean (SD)	Follow up Mean BMI, mean (SD)	Change, mean (SD)	*P** within the same group
Intervention	31.16 (6.27)	30.99 (6.44)	- 0.16 (1.58)	0.464
Control	31.98 (5.48)	32.09 (5.47)	0.11 (0.69)	0.231
Independent sample t-test: *P*=0.259 * *P* value by paired sample T-test				

5.7.3 HbA1c

Table 18 and figure 4 show the changes in HbA1c for both groups after the intervention. HbA1c decreased significantly for the intervention group [Mean (SD) 0.7763 (1.308)], while it decreased marginally for the control group [Mean (SD) 0.120 (0.9449)]. There was statistically significant difference in HbA1c change between the intervention and the control groups.

Table 18: Baseline and follow up HbA1c

	Baseline HbA1c (SD)	Follow up HbA1c (SD)	Change (SD)	*P** within the same group
Control	7.59 (1.571)	7.469 (1.286)	- 0.120 (0.9449)	0.335
Intervention	8.8 (1.98)	8.024 (1.573)	- 0.7763 (1.308)	.000
Independent sample t-test: *P*=0.002 * *P* value by paired sample T-test				

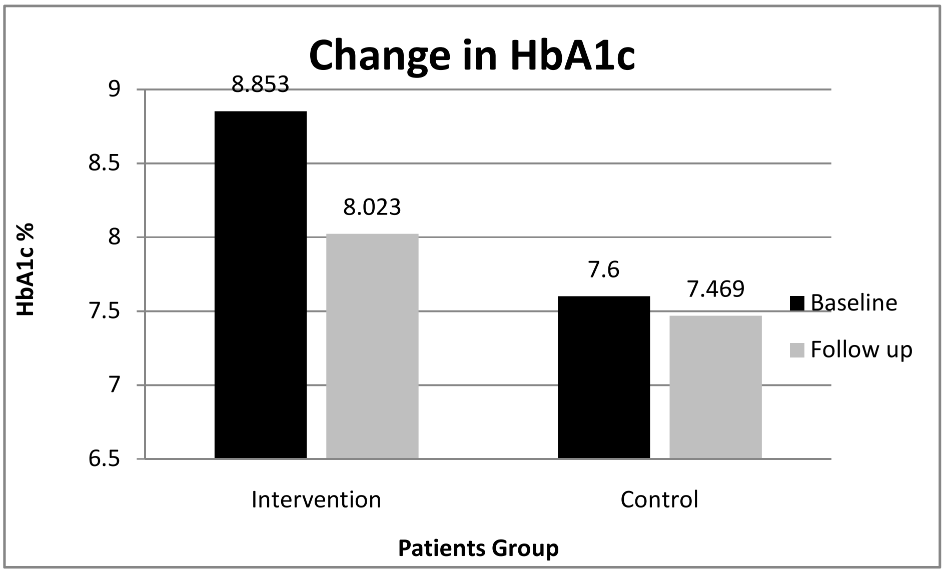


Figure 4: Changes in HbA1c in the intervention and control groups

Direction of change of HbA1c

Table 19 and Figure 5 show the statistically significant difference between the intervention and control groups in the number of patients whose HbA1c either increased or decreased significantly (an HbA1c change of more than 0.5%) from baseline .

Table 19: Direction of changes in HbA1c (N=108)

	No change, N (%)	Decreased, N (%)	Increased, N (%)
Intervention	4 (8)	25 (50)	2 (4)
Control	3 (5.2)	11 (18.9)	12 (20)
P (Chi square test): 0.005			

The number of patients in whom HbA1c decreased significantly was higher in the intervention group compared to the control group.

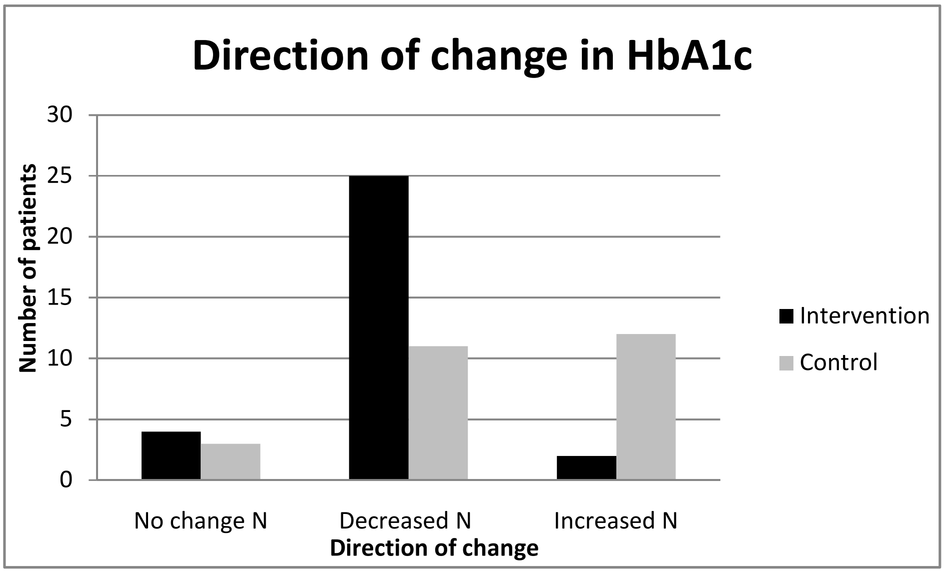


Figure 5: Direction of changes in HbA1c at follow up visit

The number of patients whose HbA1c decreased to below or equal to 7 in the intervention group was 5 (10%), while it was 3 (5.17%) in the control group (*P*= 0.436).

5.7.4 Fasting blood glucose

The change in fasting blood glucose was also in favor of the intervention group. The mean decrease in FBG was 30.617 mg/dL in the intervention group, while it increased by about 16 mg/dL in the control group (Table 20 and Figure 6).

Table 20: Mean changes in FBG in the intervention and control groups

	Baseline FBG, mg/dL, mean (SD)	Follow up FGB, mg/dL, mean (SD)	Change, mg/dL, mean (SD)	*P** value
Intervention	185.4 (73.28)	154.79 (54.7)	- 30.61 (50.37)	.000
Control	139.02 (53.49)	155.19 (114.13)	16.17 (118.31)	0.306
Independent sample T-test: *P*=0.013 * *P* value by paired sample T-test				

The number of patients whose FBG fell to 130 mg/dL or below was 11 (23.4%) in the intervention group and 11 (19.3%) in the control group (*P*=0.866).

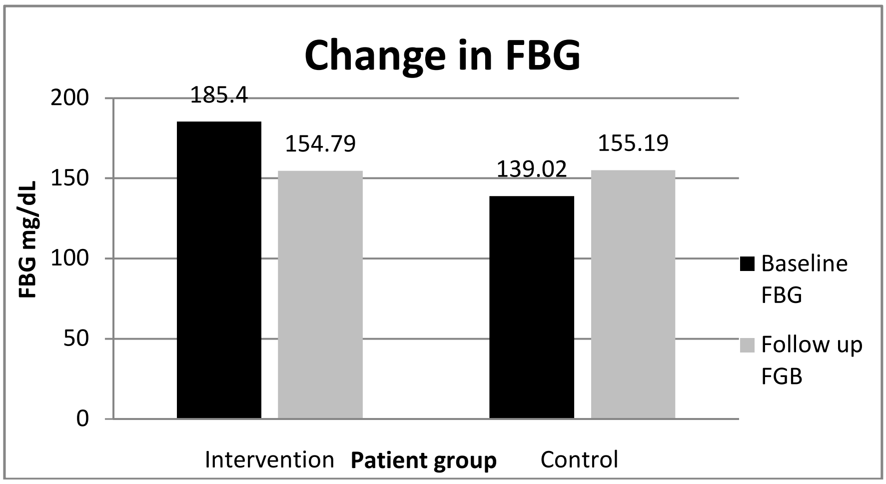


Figure 6: Changes in fasting blood glucose in the intervention and control groups

5.7.5 Blood pressure

The changes of blood pressure were not statistically significant for both groups. The decrease in systolic blood pressure was 5.05 mm Hg and 4.26 mm Hg for the control and intervention groups respectively (Table 21 and Figure 7). The number of patients in whom systolic blood pressure fell to control (Below 130 mmHg) in the intervention group was 9 (18.4%), while the number was 8 (13.8%) in the control group (*P*=0.733).The change in the diastolic blood pressure was smaller. It was 2.24 mm Hg and 1.83 mm Hg for the control and intervention groups, respectively (Table 22 and Figure 8). The number of patients in whom diastolic blood pressure fell to control (Below 80 mmHg) in the intervention group was 10 (20.0%), while the number was 5 (8.6%) in the control group (*P*=0.190).

The number of patients who gained complete control over blood pressure (below 130/80) was 4 (8.0%) in the intervention while it was 3 (5.2%) in the control group (*P*=0.345)

Table 21: Changes in systolic blood pressure at follow up

	Baseline SBP, mm Hg, mean (SD)	Follow up SBP, mm Hg, mean (SD)	Change, mm Hg, mean (SD)	*P**
Intervention	130.20 (21.45)	125.94 (18.03)	- 4.26 (22.00)	0.181
Control	131.69 (22.47)	126.64 (16.99)	- 5.05 (21.34)	0.077
P=0.852 by independent samples T-test * *P* value by paired sample T-test				

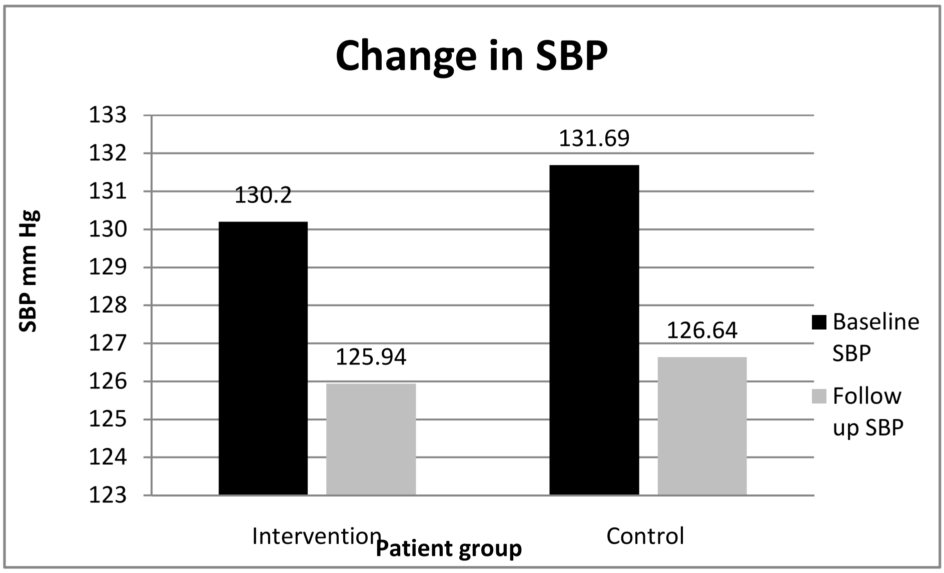


Figure 7: Changes in systolic blood pressure

Table 22: Changes in diastolic blood pressure in the intervention and control group

	Baseline DBP, mm Hg, mean (SD)	Follow up DBP, mm Hg, mean (SD)	Change , mm Hg, mean (SD)	*P** value
Intervention	75.00 (13.34)	73.16 (11.62)	- 1.83 (12.65)	0. 315
Control	75.17 (10.30)	72.93 (9.64)	- 2.24 (11.47)	0. 142
P=0.863, independent samples T-test * *P* value by paired sample T-test				

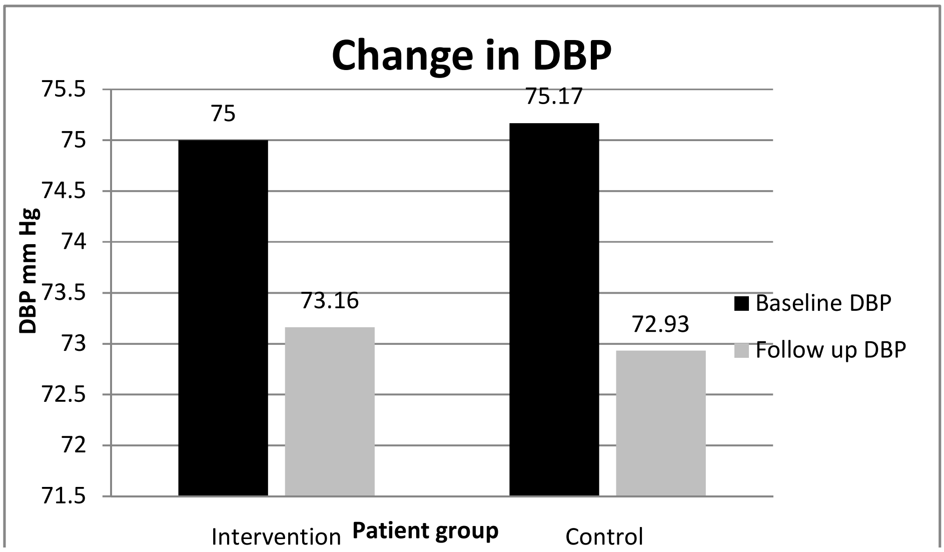


Figure 8: Changes in diastolic blood pressure in the intervention and control groups

5.7.6 Changes in fasting lipid profile

The Table 23 shows changes in the fasting lipid profile of the patients in the intervention and control groups. There was significant improvement in LDL and triglycerides in the intervention group as opposed to control.

Table 23: Change in fasting lipid profile at follow up.

	Baseline, mg/dL, mean (SD)	Follow up, mg/dL, mean (SD)	Change, mg/dL, mean (SD)	*P**
Total cholesterol				
Control	164.75 (41.561)	172.17 (34.696)	7.417 (24.318)	0.313
Intervention	174.54 (43.227)	163.23 (37.426)	- 11.308 (29.073)	0.186
***P*= 0.095 by independent T-test**				
LDL				
Control	90.92 (38.920)	99.85 (31.974)	8.923 (25.151)	0.225
Intervention	106.53 (41.773)	92.33 (34.357)	- 14.2 (33.441)	0.122
***P*=0.052 by independent T-test**				
HDL				
Control	41.246 (10.027)	41.307 (7.01)	0.61 (5.48)	0.968
Intervention	40.276 (10.01)	37.192 (6.36)	- 3.08 (8.76)	0.228
***P*=0.283 by independent T-test**				
Triglycerides				
Control	190 (87.11)	184.77 (148.123)	- 5.231 87.727)	0.833

Intervention	204.64 (135.66)	185.57 (107.07)	- 19.071 (63.005)	0.278
***P*=0.469 by independent T-test**				
* *P* value by paired sample T-test				

The number of patients in whom LDL fell to below 100 mg/dL in the intervention group was 5 (10%) in the intervention group, while it was 2 (3.44%) in the control group (*P*=0.341)

5.7.7 Change in self reported adherence to self care activities

Table 24 shows the scores for various self-care activities at the baseline and at the follow up visit for both groups. The table indicates that the subjects in the intervention group became more adherent to the various self care activities such as diabetic diet and exercise compared to their baseline level. On the other hand, there was virtually no change in the adherence of subjects in the control group to these activities.

Table 24: Self reported adherence to self care activities

	Intervention, Mean (SD)				Control, Mean (SD)				*P* between groups**
	Baseline	Follow up	Change	*P** within group	Baseline	Follow up	change	*P** within group	
Number of days‡ with diabetic diet	3.28 (2.483)	4.84 (1.822)	1.56	.000	3.34 (2.838)	3.36 (2.839)	0.017	.322	0.000
Number of days‡ with diabetic diet in the last	3.16 (2.368)	4.66 (1.722)	1.5	.000	3.21 (2.783)	3.19 (2.813)	- 0.017	.799	0.000

month as an average									
Diet	3.2200 (2.42049)	4.7500 (1.76199)	1.53	.000	3.2759 (2.79280)	3.2759 (2.81782)	0.00	1.000	0.000
Number of days‡ with five or more servings of fruit and vegetables	2.46 (1.832)	3.22 (1.433)	0.76	.000	3.24 (2.423)	3.10 (2.360)	- 0.138	.103	0.000
Number of days‡ with high fat diet	2.58 (1.540)	1.84 (1.361)	- 0.74	.000	2.93 (1.715)	2.97 (1.727)	0.034	.698	0.000
Specific diet	3.4400 (1.12776)	2.5300 (1.17112)		.000	3.6552 (1.33182)	3.0345 (1.61642)		.007	
Number of days‡	1.82 (2.608)	3.70 (2.082)	1.88	.000	2.09 (2.755)	1.97 (2.602)	- 0.12	.226	0.000

with at least 30 minutes exercise									
Number of days‡ with special kind of sport (swimming, running..)	.14 (.990)	.30 (1.313)	0.16	.209	.17 (.994)	.21 (1.120)	0.0345	.802	0.506
Exercise	.9800 (1.52181)	2.0000 (1.26974)	1.02	.000	1.1293 (1.60471)	1.0862 (1.51350)	- 0.04	.533	0.000
Number of days‡ with glucose monitoring	2.38 (2.641)	3.88 (2.545)	1.5	.000	1.97 (2.568)	2.00 (2.575)	0.03	.159	0.000
Number of days‡	.28 (1.386)	1.00 (2.176)	0.72	.007	.53 (1.657)	.47 (1.454)	- 0.069	.604	0.000

with glucose monitoring as directed by a physician as an average									
Glucose monitoring	1.3300 (1.69817)	2.4400 (1.82287)	1.11	.000	1.2500 (1.79973)	1.2328 (1.75773)	- 0.017	.799	0.000
Number of days‡ with foot check	5.76 (2.568)	6.82 (1.024)	1.06	.003	5.50 (2.793)	5.57 (2.779)	0.069	.604	0.000
Number of days‡ with shoe check	4.54 (3.240)	6.06 (2.368)	1.52	.000	3.47 (3.357)	3.79 (3.370)	0.32	.087	0.000
Foot care	5.1500 (2.63076)	6.4400 (1.49024)	1.29	.000	4.4828 (2.68682)	4.6810 (2.70914)	0.199	.087	0.002
Daily cigarettes	4.28 (14.881)	1.78 (5.116)	2.5	.117	2.83 (7.894)	3.34 (9.241)	0.517	.322	0.072

* *P* by paired sample T-test

** *P* by independent sample T-test

There has been an increase of 1.5 days in the number of days per week in which patients adhere to healthy diet in the intervention group compared to a very small increase in the control group. Similarly, the number of days per week in which the patients eat 5 servings of fruits and vegetables increased by 0.76 days in the intervention group, opposed by a decrease in the control group.

Also, the number of days in which patients exercise for more than 30 minutes increased significantly in the intervention group while it decreased in the control group.

Similar results were observed in SMBG, as it increased by 1.5 days in the intervention group while the increase in the control group was marginal.

There was also a significant increase in the number of days patients perform a foot or shoe check in the intervention group, compared to a small increase in the control group.

5.7.8 Change in knowledge about medications

The average scores of subject's knowledge about medication in both groups at baseline and at follow up are compared in table 25. The improvement in subjects' knowledge about various aspects of medication was higher in the intervention group.

Table 25: Mean knowledge about medications in the two groups at baseline and at follow up

	Baseline knowledge score about medication, mean (SD)	Follow up knowledge score about medication, mean (SD)	Change in knowledge score, mean (SD)	*P**
Intervention	3.74 (1.94)	4.66 (1.54)	0.91 (0.83)	0.000
Control	3.94 (2.01)	3.98 (2.00)	0.03 (0.17)	0.096
P=0.000 by independent samples T-test * *P* by paired sample T-test				

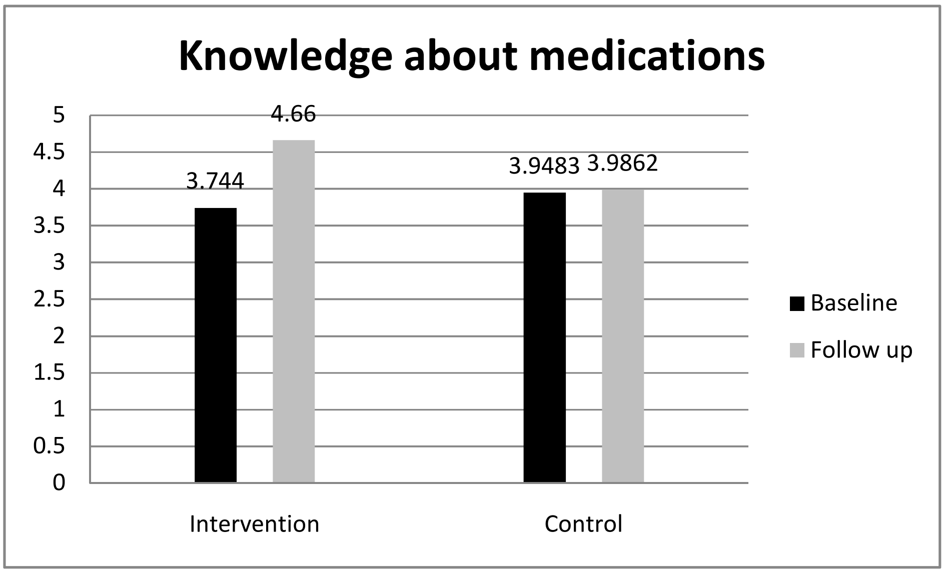


Figure 9: Changes in knowledge about medications in the intervention and control groups

At the follow up, the number of patients who had appropriate knowledge about all aspects of medications (those who were given a score of 7) was 8 (16%) and 9 (15.5%) (Chi square test): *P*= 0.945) in the intervention and control groups, respectively.

The percent in the intervention group increased by 6.2%, while the percent increase in the control group was 0.4%.

5.7.9 Change in adherence to medications

Table 26 compares the number of patients that were adherent to medications at the follow up versus the baseline. The table indicates that the percentage of people that became adherent to medications increased more significantly in the intervention group.

Table 26: Proportion of patients that were completely adherent at baseline (N=124) and at follow up (N=108)

Number of patients that are adherent to medications	Baseline N (%)*	Follow up N (%) **	Change percent	*P* value (Chi square test)
Intervention	48 (78)	48 (96)	18	0.591
Control	48 (76)	47 (81)	5	

* percent from baseline number of patients in each group

** percent from follow up number of patients in each group

5.7.10 Treatment related problems

Table 27 shows a comparison between the intervention and control groups in the outcome of treatment related problems. Ninety two percent of the identified TRPs were corrected in the intervention group compared to only 3.4 % in the control group. This represents a 27 times benefit in the intervention group compared with control group.

Table 27: Outcomes of treatment related problems

Outcome	Total population, N (%)	Intervention, N (%)	Control, N (%)	*P* (Independent sample T-test)
Number of recommendations	489	259	230	
Number of TRPs corrected	248 (50.7)	240 * (92.6)	8 (3.4)	
Resolved **	76 (15.5)	69 (26.6)	7 (3.0)	0.000
Improved	47 (9.6)	36 (13.9)	11 (4.8)	0.023
No change	182 (37.2)	17 (6.6)	165 (71.7)	0.000
Worsened	18 (3.7)	8 (3.0)	10 (4.3)	0.616
Drug added	35 (7.1)	34 (13.1)	1 (0.4)	0.000
Prevented	6 (1.2)	6 (2.3)	0 (0)	0.011
Test performed	13 (2.6)	7 (2.7)	6 (2.6)	0.723
No data	73 (14.9)	49 (18.9)	24 (10.4)	0.148

* Corrected problems include the implemented + on patient level for intervention group.

** Resolved indicates that therapeutic outcome was achieved

Table 28: Statistical comparison for outcomes of treatment related problems

Outcome	Total population (N=124), mean per patient (SD)	Intervention (N=61), mean per patient (SD)	Control (N=63), mean per patient (SD)	*P* (Independent sample T-test)
Resolved *	0.6129 (0.95176)	1.13 (1.08)	0.111 (0.36)	0.000
Improved	0.3790 (0.76075)	0.59 (0.91)	0.17 (0.49)	0.002
No change	1.4677 (1.66472)	0.26 (0.51)	2.63 (1.55)	0.000
Worsened	0.1452 (.43605)	0.11 (0.36)	0.17 (0.49)	0.447
Drug added	0.2823 (0.59210)	0.55 (0.74)	0.01 (0.12)	0.000
Prevented	0.0484 (.21545)	0.09 (0.30)	0 (0)	0.013
Test performed	0.1048 (0.30759)	0.11 (0.32)	0.09 (0.29)	0.725
No data	0.5887 (1.32525)	0.80 (1.58)	0.38 (0.97)	0.079

* Resolved indicates that therapeutic outcome was achieved

5.7.11 Starting new drugs

In the intervention group, statin therapy was added to 8 subjects, and the statin dose was increased for another 8 subjects.

Aspirin was started for 6 subjects that were not previously on it despite the presence of indication for antiplatelet therapy.

An ACE inhibitor or ARB was started for 11 subjects that had either hypertension and treated with other antihypertensives, or have untreated protienuria.

5.8 Examples on treatment related problems

Table 29 includes examples on the TRPs identified in the study patients.

Table 29: Examples on treatment related problems

Unnecessary drug therapy	
Drug use without an indication	A 46 year old female taking furosemide without any clear indication.
Treatment should be stepped down	68 year old male treated with insulin glargine and rapid acting insulin, and has at least one episode of hypoglycemia daily.
Untreated condition	
Untreated condition	69 year old male with elevated LDL and not treated for dyslipidemia.
Efficacy treatment related problems	
More effective drug is available	58 year old male with hypertension and being treated with a beta blocker.
Need for additional/combination therapy	64 year old male with diabetes and an HbA1c of 8 % treated with metformin alone
Efficacy dosage regimen issue	63 year old female with hypertension and receiving bisoprolol 5 mg 1x2.
Safety treatment related problems	
Current drug is contraindicated/ unsafe for patient condition and	60 year old female with CKD (GFR<60) and using metformin

should be stopped, monitored.	
Safer drug therapy is recommended	61 year old male with dyslipidemia on atorvastatin and has symptoms of myopathy.
Allergic reaction or an undesirable effects	60 year old female with hypertension treated with atenolol 100 and complaining of sexual dysfunction.
Safety dosage regimen issues	52 year old male with diabetes treated with insulin and suffers hypoglycemia due to inappropriate timing of insulin injection.
Inappropriate knowledge	
The patient is not instructed or does not understand important information regarding his medications	53 year old female with diabetes who does not know the correct timing for glibenclamide with regards to meals.
The patient is not instructed or does not understand non-pharmacological therapy or self care advice	Patient does not know proper foot care.
Inappropriate adherence	
A problem in patients' adherence to medications	Patient skipping some of her insulin injections despite taking usual meals.
A problem in patients' adherence to self care activities	Patient not adherent to low fat diet and takes 5 fatty meals per week.
Miscellaneous	
Need for frequent monitoring	Patient who has not performed a lipid profile for more than 2 years

Need for diagnostic test	A patient with a low hemoglobin and needs an anemia work up

6. Discussion:

Pharmacists enter into a collaborative relationship with patients where pharmacists bring medication-related expertise to assist patients, and patients provide opportunity and authority for the pharmacists to assist them (Buerki and Vottera, 1996). Providing care consistent with this philosophy, pharmacists seek to identify, resolve and prevent real and potential drug-related problems (Hepler and Strand, 1990).

Diabetes is a leading cause of death in most countries, both developed and developing. In addition, it is reaching epidemic proportions in many newly industrialized nations. Most statistics expect a doubling of the epidemiology of diabetes between the years 2000 and 2030, with a big proportion of that increase in the Middle East, sub-Saharan Africa, and India. (Wild, *et al.*, 2004).

Since the complications of diabetes are various, a big effort must be made to achieve metabolic control of the disease. Unfortunately, despite all the effort, a large percentage of persons with diabetes remain uncontrolled and have high HbA1c levels that can be much above the recommended goals. (Boegner, *et al.*, 2008).

The prevalence of diabetes in Jordan has increased dramatically over the period 1994-2004, and the patients are likely to benefit from programs that aim at encouraging non-pharmacological behaviors to gain control over diabetes (Ajlouni, *et al.*, 2007).

This prospective study included 124 patients over the study period. Fifty three percent of the patients were females.

Baseline data:

The baseline demographic data of the intervention and control groups are generally similar (see table). A slight difference was observed in the gender distribution of subjects in the control group. But the current evidence indicates that gender does not affect glycemic control in diabetic patients (Jonsson, *et al*., 2000; Barre, *et al*., 2007)).

Alarmingly, about ninety percent on the patients enrolled in the study were overweight or obese. This is similar to the findings of Ajlouni, *et al*. who found that the mean BMI of their sample was 30.46, which is classified as obesity (Ajlouni, *et al*., 2007), and also with the findings of Qteishat, *et al*. (2010) who found that 98% of the patients enrolled in their study were either overweight, obese, or morbidly obese.

On the other hand, some of the baseline clinical data varied between the control and intervention groups. The mean glycosylated hemoglobin and the fasting blood glucose were higher in the intervention group; HbA1c mean was 8.75% for the intervention and 7.6% for the control, while mean fasting blood glucose was 178.36 mg/dL for the intervention and 138.61 mg/dL for the control group, which makes the intervention group harder to control. The duration of diabetes was also longer in the intervention group, which may explain the worse glycemic control among these patients.

The prevalence of symptoms of peripheral neuropathy and retinopathy was very high as more than half of the patients reported having their symptoms. This is higher than what have been observed by Qteishat, *et al*. (2010) who reported that the prevalence of neuropathy and retinopathy were 18% and 25%, respectively (Qteishat, *et al*., 2010), but very similar to the

recent study that demonstrated the prevalence of painful diabetic neuropathy in diabetic population in Jordan to be 57.5% (Jambart, *et al*., 2011).

Forty eight percent of the subjects in the study received insulin with or without oral hypoglycemic agents. The most commonly used antidiabetic agent was metformin. The frequency of insulin use was higher than observed by Qteishat, *et al*. (2010) who found that 27.5% of their patients used insulin, the same was true for metformin as they found that 80% of their patients used it compared to 88% in our study (Qteishat, *et al*., 2010).

Only 16 (12.9 percent) of patients had appropriate knowledge about all aspects of their medications. Most of the patients had some knowledge about the dose and frequency of use. The most lacking information was regarding the safety and efficacy parameters and the ability to distinguish between different trade names of the same medication. The knowledge score was lower than that observed by similar studies. McPherson, *et al*. (2008) reported that patient in their study had a median score of 5 on a scale of 8, while the patients in our study had a score of 3.65 on a scale of 7. Our result was similar to that of Qteishat, *et al*. (2010), in which the total score of knowledge about medications for the sample population was 3.8 out of 7 (Qteishat, *et al*., 2010).

A large percentage (78% in the intervention group and 76% in the control group) of the study participants were adherent to their medications. Patients reported stopping taking their medications for no obvious reason, or when they experienced side effects as the main causes of non-adherence to medications. These results are similar to the findings of Weissberg, *et al*. (1995) in which only 25 percent of the patients admitted skipping one or more of their insulin shots (Weissberg, *et al*., 1995). On the other hand, prevalence of non-adherence was lower than

that reported by Qteishat, *et al*. (2010) where 41% of patients were involved in medication non-adherence to at least one medication (Qteishat, *et al*., 2010).

An important factor in the treatment of diabetes is adherence to self care activities. Most patients reported that they adhere to a diabetic diet 3 to 4 days a week. Most patients ate 5 servings of fruits or vegetables a day in 2 or less days of the week. These results are lower than those observed by Qteishat, *et al*. (2010) who reported that the mean days per week in which patients adhered to specific diabetic diet or ate 5 servings of fruits or vegetables was more than five 5 (Qteishat, *et al*., 2010).

The average number of days per week in which the patients exercised for 30 minutes or more was 1.95, and a very small number of patients reported performing other types of exercise like swimming or running. This is much different from the results of Qteishat, *et al*. (2010) who reported that patients exercised more than 30 minutes a day in 6.25 days per week, which might be due to inappropriate application of the questionnaire (Qteishat, *et al*., 2010).

Patients in our study performed foot care in most days of the week (5.59 day per week on average) as a part of their religious obligations (Wodou': washing certain parts of the body including feet preparing for prayer). But most of them are not aware of the importance of foot care for prevention of diabetic foot or ulcerations.

The average number of treatment related problems was 3.94 per patient. The most frequent type of treatment related problems was efficacy treatment related problems (40%), followed by inappropriate adherence to medications and life style modifications. The average number of treatment related problems identified by Qteishat, *et al*. (2010) was higher (7.5), which might be due to different clinical setting or different background of the patients. The most frequent TRP

type in their study was the need for more frequent monitoring and diagnostic test (Qteishat, *et al*., 2010).

The high abundance of efficacy treatment related problems indicates that patients were not receiving optimal therapy, which means that their outcomes could have been better if their treatment was optimized.

Follow up data:

As a result of the clinical pharmacist intervention, after the three month period there was statistically significant improvement in a number of clinical outcomes.

There was a reduction in mean weight of patients in the intervention group, while there was a slight increase in mean weight of the control group, however difference in weight change did not reach statistically significant level, probably, due to short follow up time. Other studies reported a larger decrease in BMI, but over a longer follow up period. Clifford, *et al*. (2005) reported that a 0.6 Kg/m^2 decrease in BMI in the intervention group over a period of 12 months compared to a 0.1 Kg/m^2 increase in the control group (Clifford, *et al*., 2005).

The HbA1c, the main indicator of glycemic control, decreased significantly in the intervention group as compared to the control group (0.77% in the intervention versus 0.12% in the control), which was similar to the findings of Jaber, *et al*. (1996), Coast-Senior, *et al*. (1998), Gong, *et al.,* (1999), Davidson, *et al*. (2000), and Rothman, *et al*. (2005). Those studies reported various differences in HbA1c over different follow up periods, for example Rothman, *et al*. (2005) reported 2.5% decrease in HbA1c in the intervention group compared to a 1.6 decrease in the control group over a period of 12 months (Rothman, *et al*., 2005).

Clinically significant decrease in HbA1c (a decrease of more than or equal to 0.5%) was observed in fifty percent of the subjects in the intervention group as compared to only 19 percent in the control group (*P*=0.005).

The number of patients who gained full glycemic control (HbA1c fell to below 7) was also higher in the intervention group (10% in the intervention group and 5.17% in the control group) being with agreement with the findings of Irons, *et al*. (2002).

In concordance to the studies of Jaber, *et al*. (1996) and Coast-Senior, *et al*. (1998), there has been a reduction in the value of the fasting blood glucose in the intervention group as opposed to an increase in the value of the control group (*P*=0.013). The number of patients in whom FBG fell to below 130 mg/dL was similar in the two groups.

Changes in systolic and diastolic blood pressure were not statistically significant in either of the study groups in contrast to other studies, e.g., Rothman, *et al*. (2005) where systolic blood pressure was more significant in the intervention as compared to the control group. Lack of changes in blood pressure in our study may be explained by the fact that it was fairly controlled at the baseline (mean blood pressure for the total sample at baseline 129/75 mm Hg).

However, the number of patients in whom the blood pressure fell to control was higher in the intervention group; 9 in the intervention versus 8 in the control in systolic blood pressure, 10 in the intervention versus 5 in the control group in diastolic blood pressure, and 4 in the intervention versus 3 in the control in systolic over diastolic blood pressure.

The primary lipid goal in prevention of cardiovascular disease is LDL (American Diabetes Association, Standards of Medical Care in Diabetes, 2010). In spite of lack of improvement in

total cholesterol, HDL and triglycerides, there was almost significant (p=0.052) difference in the LDL change between the intervention and control.

The number of patients in which LDL fell to below target was 5 (10%) in the intervention group, while it was 2 (3.44%) in the control group.

These results are similar in nature to those observed by Chung, *et al*. (2011) where patients in the intervention group achieved a 26.4% reduction in LDL compared to a 12% in the control group (Chung, *et al*., 2011). According to the Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults, every 1 percent decrease in LDL cholesterol reduces risk for CHD by about 1 percent (Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults, 2002). In our study, the mean decrease in LDL in the intervention group was by 13.3%, as opposed to 9.8% increase in the control group.

There was also a significant improvement in patients' knowledge about medications in the intervention group (25%) compared to a very small improvement in the control group (1%) (*P*=0.000). The percentage of patients who had enough knowledge about medications also increased significantly in the intervention group (6.2%) as compared to the control group (0.4%). Similar improvement was observed in the study by Van Veldhuizen-Scott, *et al.* (1995) whose results indicated a significant increase in patient understanding of diabetes medications and medications for concomitant illnesses and an increase in knowledge about glucose monitoring.

Similar to the results of Altavela, *et al*. (2008), the percentage of patients adherent to their medications increased (from 78 to 96 percent) in the intervention group, compared to only a 5 percent increase in the number of adherent patients in the control group.

Even better results were observed in patients' adherence to self care activities. In the intervention group, there was a statistically significant improvement from baseline for most reported self care activities. There was no statistically significant difference in the control group in any of the reported self care activities. These results are similar to those in the study by Mehuys, *et al*. (2010) who reported an increase in patients' adherence to self care activities for the management of diabetes as a result of pharmacist intervention (Mehuys, *et al*., 2010).

Outcomes of treatment related problems at follow up

The number of treatment related problems identified in the intervention group and the control group was similar at baseline.

The number of treatment related problems corrected (that include implemented and on patient level) in the intervention group was thirty times higher than that in the control group (240 vs. 8).

This is similar to the results of Fornos, *et al*. (2006) who reported that pharmacist intervention led to resolving 61.9% of the treatment related problems that appeared in their intervention group (Fornos, *et al*. 2006).

The number of treatment related problems that were completely resolved (i.e., their clinical outcome achieved) in the intervention group was ten times higher than the control group. This

corresponds to an average of 1.13 problems completely resolved per patient in the intervention group compared to 0.111 problems per patient in the control group (*P*=0.000).

The number of treatment related problems that had outcome improved but not completely resolved was also higher in the intervention group (36 in the intervention vs. 11 in the control).

TRPs that had no change in outcome were more prevalent in the control group. An average of 2.63 TRP per patient did not change at follow up in the control group, compared to only 0.26 TRP per patient in the intervention group (*P*=0.000).

The rate of starting new drugs was higher in the intervention group: a mean of 0.55 medications per patient compared to 0.01 medications per patient in the control group (*P*=0.000). These medications included aspirin for the primary or secondary prevention of vascular diseases, statins for the treatment of dyslipidemia or for the primary prevention of vascular disease, ACE inhibitors or ARBs for the treatment of hypertension or proteinuria. These results are similar to those of Clifford, *et al*. (2005) who found that implementation of pharmaceutical care program led to an increase in the use of ACEIs by 19.6% in the intervention group compared to only 8% increase in the control group. In their study, there has been an increase in the use of antiplatelet medication by 16.3%in the intervention group compared to 6.9% in the control group. Unfortunately, due to the drop out of some patients in the follow up, there was no data for 73 treatment related problems.

7. Conclusion

- The majority of type 2 diabetic patients who attend University Endocrine clinic have average disease duration about 10 years, are either overweight or obese (90%), they have high prevalence of hypertension (82%) and dyslipidemia (76%), about half of them have retinopathy, and also half of them have peripheral neuropathy
- Before the clinical pharmacist intervention, diabetic patients had poor glycemic control (mean HbA1c 8.16 % and FBS 156 mg/dL), but rather fair blood pressure control (mean 129/75 mm Hg) and LDL (99.2 mg/dL).
- Patients enrolled in the study have suboptimal adherence to self-care activities such as healthy diet, sports, self blood glucose monitoring, and foot care (spending on average 2-3 days a week in such activities).
- A very small proportion of patients (13%) had appropriate knowledge of their medications, and majority of them (77%) were adherent to medications.
- The average number of treatment related problems per patient at baseline was 4, two-thirds of TRPs were related to diabetes itself, and about a quarter of TRPs were related to insulin.
- Among the types of treatment related problems, efficacy issues were the most frequent (40%).
- Most of clinical pharmacist's recommendations (94%) were accepted by physicians, and most of those accepted were implemented (95%).
- Clinical pharmacist's intervention has resulted in significant improvement of the following clinical outcomes:

- HbA1C (decrease by 0.78% versus 0.12% in the control);

- FPG (31 mg/dL improvement as compared to 16 mg/dL worsening in the control);
- Tendency in decrease in LDL (14 mg/dL decrease versus 9 mg/dL increase in the control);
- Most domains of self-reported daily activities, except sports and smoking cessation;
- Knowledge about medications (score increase of 0.91 versus 0.03 in the control);
- The number of TRPs resolved, improved, or prevented was significantly higher in the intervention group
- The study supports the role of clinical pharmacists in the ambulatory care environment, in collaboration with primary care physicians, in reaching therapeutic goals in diabetic patients.
- The positive outcomes achieved in several clinical parameters implicated as risk factors in the development of macro- and micro-vascular events occurred due to a combination of improvements in the use of the drugs, plus the educational intervention which has significantly increased the awareness about diabetes and its complications.
- Our study shows that clinical pharmacists can play an important role in the management of type 2 diabetics.

Limitations

There are several limitations to our study. The study was performed in one medical center, and included only insured patients, which might limit generalizability. Another limitation is the relatively short follow up period which was not enough to detect changes in some of the desired outcomes of the study. Finally, several measures were based on patients' self report. We tried to limit the bias by focusing on objective measures of clinical outcomes.

Strengths

Although our study had some limitations, it had some strength points over similar studies. First, patient selection was completely random in contrast to other studies in which patients were assigned to the intervention or control group according to certain factors. Second, the study included a control group from the same background and circumstances, and the number of patients in the two groups was almost identical, while other studies either did not include a control group, or used a historical control group. Third, the study attempted to comprehensively measure clinical outcomes in diabetic patients, both clinical and humanistic. Fourth, the number of patients included in the study was higher than that in many other studies in similar populations, which makes its results more generalizable.

Future studies

Future studies that may overcome the limitations of this study should include a larger number of patients, with a longer follow up period, and being conducted in more than one hospital or medical center.

REFERENCES

AbuRuz, S. Boulatova, N. and Yousef, M. (2006), validation of a comprehensive classification for treatmwnt related problems. Pharmacy world and science, 28, 222-2232.

AbuRuz, S. (2009a), Validation and reliability of the Arabic adherence to medication questionnaire in the Jordanian population. Manuscript is being reported for publication

AbuRuz, S. (2009a), Validation and reliability of the Arabic adherence to self care activities questionnaire in the Jordanian population. Manuscript is being reported for publication

Ajlouni, K. Jaddou, H. and Batieha, A. (1998), Diabetes and impaired glucose tolerance in Jordan: prevalence and associated risk factors. **Journal of Internal Medicine**; 244: 317–323.

Ajlouni, K. Khader, Y.S. Batieha, A. Ajlouni, H. and El-Khateeb, M. (2007), An increase in prevalence of diabetes mellitus in Jordan over 10 years**. J Diabetes Complications**.; 22(5):317-24. Epub 2008 Apr 16.

Altavela, J.L. Jones, M.K. and Ritter, M. (2008), A prospective trial of a clinical pharmacy intervention in a primary care practice in a capitated payment system**. Journal of Managed Care Pharmacy**; 14(9):831-43.

American college of clinical pharmacy (2008), The definition of clinical pharmacy, **Pharmacotherapy.**; 28(6):816-7.

American Diabetes Association. (2004). Diabetes mellitus and exercise. **Diabetes Care;** 27(Suppl 1), S58–S62.

American Diabetes Association, (ADA) (2010). Standards of Medical Care in Diabetes. **Diabetes Care**, Volume 33, Supplement 1, S11-S61

American Diabetes Association, (ADA) (2010). Diagnosis and Classification of Diabetes Mellitus. **Diabetes Care**, Volume 33, Supplement 1, S62-S69

American Diabetes Association, (ADA) (2007). Nutrition Recommendations and Interventions for Diabetes: a position statement of the American Diabetes Association. **Diabetes Care**.; 30 Suppl 1:S48-65.

Bailey, C.J. (1992), Biguanides and NIDDM. **Diabetes Care**; 15:755.

Bailey, C.J. and Turner, R.C. (1996), Metformin. **New England Journal of Medicine**; 334:574.

Barre, D.E. Mizier-Barre, K.A. Griscti, O. and Hafez, K. (2007), Gender: does it have role has a role in glycaemic control in Caucasians with well controlled type 2 diabetes? **Int J Diabetes & Metabolism** 15: 76-80

Berringer, R. Shibley, M.C. Cary, C.C. Pugh, C.B. Powers, P.A. and Rafi, J.A. (1999), Outcomes of a community pharmacy-based diabetes monitoring program. **Journal of American Pharmaceutical Association** (Wash); 39(6):791-7.

Bianchi, C. and Miccoli, R. (2008), Primary Prevention of Cardiovascular Disease in People with Dysglycemia, **Diabetes Care**, Volume 31, Supplement 2, S208-S214

Boegner, C. Fontbonne, A. Gras-Vidal, MF. Mouls, P. and Monnier, L. (2008), Evaluation of a structured educational program for type 2 diabetes in private practice**. Diabetes Metab**; 34(3):243-9.

Bressler, R. and Johnson, D.G. (1997), Pharmacological regulation of blood glucose levels in non-insulin dependent diabetes mellitus. **Arch Intern Med**; 28;157(8):836-48.

Brwon, E.S. (2003), Social and psychological factors and psychosomatic syndromes. **Advances in Psycosomatic medicine**, 24, 42-50

Buerki, R.A. Vottera, L.D. (1996), The purpose of professions in society. In: Knowlton, C.H., Penna, R.P. (Eds.). Pharmaceutical care. Chapman and Hall, New York.

Chung, J.S. Lee, K.K. Tomlinson, B. Lee, V.W. (2011), Clinical and economic impact of clinical pharmacy service on hyperlipidemic management in Hong Kong. **Journal of Cardiovascular Pharmacology and Therapeutics.** 16(1):43-52.

Clifford, R.M. Davis, W.A. Batty, K.T. Davis, T.M. and Fremantle Diabetes Study (2005), Effect of a pharmaceutical care program on vascular risk factors in type 2 diabetes: the Fremantle Diabetes Study. **Diabetes Care**; 28(4):771-6.

Coast-Senior, E.A. Kroner, B.A. Kelley, C.L. and Trilli, L.E. (1998), Management of patients with type 2 diabetes by pharmacists in primary care clinics. **The Annals of Pharmacotherapy**; Vol. 32, No. 6, pp. 636-641

Cranor, C.W., Bunting, B.A. and Christensen, D.B. (2003), The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program **Journal of American Pharmaceutical Association**; 43(2):173-84.

Davidson, M.B. Karlan, V.J. and Hair, T.L. (2000), Effect of a pharmacist-managed diabetes care program in a free medical clinic. **American Journal of Medical Quality**; 15(4):137-42.

DeFronzo, R.A. and Goodman, A.M. (1995), Efficacy of metformin in patients with non-insulin dependent diabetes mellitus. The Multicenter Metformin Study Group. **New England Journal of Medicine**; 333:541.

The Diabetes Control and Complications Trial Research Group (1993), DCCT: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. **New England Journal of Medicine**; 329:977–986

Expert Panel on Detection, and Treatment of High Blood Cholesterol in Adults. Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). **JAMA** 2001; 285:2486–2497.

Fehse, F. Trautmann, M. Holst, J.J. Halseth, A.E. Nanayakkara, N. Nielsen, L.L. Fineman, M.S. Kim, D.D. and Nauck, M.A. (2005), Exenatide augments first- and second-phase insulin secretion in response to intravenous glucose in subjects with type 2 diabetes. **Journal of Clinical Endocrinol Metabolism**; 90:5991.

Fornos, J. Andre´s, N.F. Andre´s, J.C. (2006), A pharmacotherapy follow-up program in patients with type-2 diabetes in community pharmacies in Spain, **Pharm World Sci**.;28(2):65-72.

Fuhlendorff, J. Rorsman, P. and Kofod, H. (1998), Stimulation of insulin release by repaglinide and glibenclamide involves both common and distinct processes. **Diabetes**; 47:345.

Gangji, A.S. Cukierman, T. and Gerstein, H.C. (2007), A systematic review and meta-analysis of hypoglycemia and cardiovascular events: a comparison of glyburide with other secretagogues and with insulin. **Diabetes Care**; 30:389.

Garrett, D.G. and Bluml, B.M. (2005), Patient self-management program for diabetes: first-year clinical, humanistic, and economic outcomes. **Journal of American Pharmaceutical Association**; 45(2):130-7.

Gerber, R.A. Liu, G. and McCombs, J.S. (1998), Impact of pharmacist consultations provided to patients with diabetes on healthcare costs in a health maintenance organization. **American Journal of Managed Care**; 4(7):991-1000.

Gong, C., Hasson, N. and Lurn, B. (1999), Impact of a diabetes disease management clinic on the total glycosylated hemoglobin of patients with type 2 diabetes mellitus. **Journal of Managed Care Pharmacy**: 511-515.

Guirguis, L. (2003). Diabetes: Are the pharmacists making an impact on patient outcome? **Canadian Pharmacist Journal**, vol 136:24-8.

Hepler, C.D. and Strand, L.M. (1990), Opportunities and responsibilities in pharmaceutical care. **American Journal of Hospital Pharmacy**; 47(3):533-43.

Hermann, L.S. Schersten, B. and Bitzen, P.O. (1994), Therapeutic comparison of metformin and sulfonylurea, alone and in various combinations. A double-blind controlled study. **Diabetes Care**; 17:1100.

Hollander P.A. Schwartz, S.L. Gatlin, M.R. Haas, S.J. Zheng, H. Foley, J.E. and Dunning, B.E. (2001), Importance of early insulin secretion: comparison of nateglinide and glyburide in previously diet-treated patients with type 2 diabetes. **Diabetes Care**; 24(6):983-8.

Holstein, A. Plaschke, A. and Egberts, E.H. (2001), Lower incidence of severe hypoglycaemia in patients with type 2 diabetes treated with glimepiride versus glibenclamide. **Diabetes and Metabolism Research and Reviews**; 17:467.

Hudson, S. McAnaw, J. and Johnson, J. (2007), The changing roles of pharmacists in society. **JSME**;1:22-34.

Inzucchi, S.E. Maggs, D.G. Spollett, G.R. Page, S.L. Rife, F.S. Walton, V. and Shulman, G.I. (1998), Efficacy and metabolic effects of metformin and troglitazone in type II diabetes mellitus. **New England Journal of Medicine**; 338:867.

Irons, B.K. Lenz, R.J. Anderson, S.L. Wharton, B.L. Habeger, B. and Anderson, H.G. (2002), A retrospective cohort analysis of the clinical effectiveness of a physician-pharmacist collaborative drug therapy management diabetes clinic. **Pharmacotherapy**; 22(10):1294-300.

Iwamoto, Y. Kosaka, K. Kuzuya, T. Akanuma, Y. Shigeta, Y. and Kaneko T. (1996), Effects of troglitazone: a new hypoglycemic agent in patients with NIDDM poorly controlled by diet therapy. **Diabetes Care**; 19:151.

Jaber, L.A. Halapy, H. Fernet, M. Tummalapalli, S. and Diwakaran, .H (1996), Evaluation of a pharmaceutical care model on diabetes management. **Annual Pharmacotherapy**;30(3):238-43.

Jambart, S., Ammache Z., Haddad, F., Younes, A., Hassoun, A., Abdalla, K., Abou Selwan, C. Sunna , N., Wajsbrot, D. and Youseif, E. (2011), Prevalence of painful diabetic peripheral neuropathy among patients with diabetes mellitus in the Middle East region. **The Journal of International Medical Research**; 39:366-377.

Johnson, S.B. (1992), Methodological issues in diabetes research. **Diabetes Care** 15: 1658-1667.

Jonsson, P.M. Sterky, G. Gåfvels, C. and Ostman, J. (2000), Gender equity in health care: the case of Swedish diabetes care. **Health Care Women Int**.; 21(5):413-31.

Kelly, C. and Rodgers, P. (2000), Implementation and evaluation of a pharmacist-managed diabetes service. **Journal of Managed Care Pharmacy**: 488-93

Luna, B. and Feinglos, M. N. (2001), Oral agents in the management of type 2 diabetes mellitus. **American Family Physician**, 63, 1747-1756

McPherson, M.L. Smith, S.W. Powers, A. and Zuckerman, I.H. (2008), Association between diabetes patients' knowledge about medications and their blood glucose control. **Res Social Adm Pharm**; 4(1):37-45.

Mehuys, E. Van Bortel, L. De Bolle, L. Van Tongelen, I. Annemans, L. Remon ,J.P. and Giri, M. (2010), Effectiveness of a community pharmacist intervention in diabetes care: a randomized controlled trial. **J Clin Pharm Ther**.; 8. doi: 10.1111/j.

Meneilly, G.S. Ryan, E.A. Radziuk, J. Lau, D.C. Yale, J.F. Morais, J. Chiasson, J.L. Rabasa-Lhoret, R. Maheux, P. Tessier, D. Wolever, T. Josse, R.G.and Elahi, D. (2000), Effect of acarbose on insulin sensitivity in elderly patients with diabetes. **Diabetes Care**; 23:1162.

Nathan, D. Buse, J. Davidson, M. Heine, R. Holman, R. Sherwin, R and Zinman, B. (2006), Management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. A consensus statement from the American Diabetes Association and the European Association for the Study of Diabetes. **Diabetes Care**; 29:1963.

Nutrition Recommendations and Interventions for Diabetes: a position statement of the American Diabetes Association (2007), Diabetes Care;30 Suppl 1:S48-65.

Peyrot, M. Rubin, R.R. Lauritzen, T. Skovlund, S.E. Snoek, F.J. Matthews, D.R. Landgraf, R. Kleinebreil, L. and International DAWN Advisory Panel (2005), Resistance to insulin therapy among patients and providers: results of the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study. **Diabetes Care**; 28:2673.

Qteishat, R.R. (2010), **Factors affecting metabolic control in patients with type 2 diabetes mellitus**, Unpublished Master Thesis, The University of Jordan.

Ragucci, K.R. Fermo, J.D. Wessell, A.M. and Chumney, E.C. (2005), Effectiveness of pharmacist-administered diabetes mellitus education and management services. **Pharmacotherapy**; 25(12):1809-16.

Riddle, M.C. Ambrosius, W.T. Brillon, D.J. Buse, J.B. Byington, R.P. Cohen, R.M. Goff, D.C. Malozowski, S. Margolis, K.L. Probstfield, J.L. Schnall, A.and Seaquist, E.R. Action to Control Cardiovascular Risk in Diabetes Investigators (2010), Epidemiologic relationships between A1C and all-cause mortality during a median 3.4-year follow-up of glycemic treatment in the ACCORD trial. **Diabetes Care**; 33(5):983-90.

Rothman, R.L. Malone, R. Bryant, B. Shintani, A.K. Crigler, B. Dewalt, D.A. Dittus, R.S. Weinberger, M. and Pignone, M.P. (2005), A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycated hemoglobin levels in patients with diabetes. **American Journal of Medicine**; 118(3):276-84.

Schernthaner, G. Matthews, D.R. Charbonnel, B. Hanefeld, M. Brunetti, P. and Quartet Study Group. (2004), Efficacy and safety of pioglitazone versus metformin in patients with type 2 diabetes mellitus: a double-blind, randomized trial. **Journaal of Clinical Endocrinol Metabolism**; 89:6068.

Strand, L.M. Cipolle, R.J. Morley, P.C. and Frakes, M.J. (2004). The impact of pharmaceutical care practice on the practitioner and the patient in the ambulatory practice setting: twenty-five years of experience. **Current Pharmaceutical Design**.;10:3987- 4001.

Ting, R.Z. Szeto, C.C. and Chan, M.H. (2006), Risk factors of vitamin B(12) deficiency in patients receiving metformin. **Achieves of Internal Medicine**; 166:1975.

Toobert, D. Hampson, S.and Glasgow, R. (2000), The Summary of Diabetes Self-Care Activities Measure. **Diabetes care**; 23(7), 943-950.

UK Prospective Diabetes Study (UKPDS) Group (1998), UKPDS: Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). **Lancet**; 352:854–865.

van de Laar, F.A. Lucassen, P.L. Akkermans, R.P. van de Lisdonk, E.H. Rutten, G.E. and van Weel C. (2005), Alpha-glucosidase inhibitors for patients with type 2 diabetes: results from a Cochrane systematic review and meta-analysis. **Diabetes Care**; 28:154.

Van Veldhuizen-Scott, M.K. Widmer, L.B. Stacey, S.A. and Popovich, N.G. (1995), Developing and implementing a pharmaceutical care model in an ambulatory care setting for patients with diabetes. **Diabetes Education**; 21(2):117-23.

Weisssberg, J. Glasgow, A.M. Tynan, W.D. Wirtz, p. Turk, J. and ward, J. (1995), Adolescent diabetes management and mismanagement. **Diabetes Care,** vol. 18 no. 1 77-82

Wild, S. Roglic, G. Green, A. Sicree, R. and King, H. (2004), Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. **Diabetes Care**, 27, 1047-1053

Wolffenbuttel, B. and Landgraf, R. (1999), A one-year multicenter randomized double-blind comparison of repaglinide and glyburide for the treatment of type 2 diabetes. **Diabetes Care**; 22:463.

Yki-Jarvinen, H. (2004), Thiazolidinediones. **New England Journal of Medicine**; 351:1106.

Appendices

Appendix 1:

	العمر
	الجنس
	ألمهنة
	التحصيل الأكاديمي
	الحالة الزوجية
	الوزن
	الطول
	نسبة التأمين
	الدخل الشهري

Duration of diabetes	
Retinopathy (vision)	
Nephropathy	
Neuropathy (sensation)	
Education received: Diabetes Medications Diet Exercise Glucose monitoring Foot care Smoking	
Random Blood Glucose	, Date
HbA1c (the latest 3 measures)	, Date
Blood pressure	, Date
Cholesterol	, Date
LDL	, Date
HDL	, Date
TG	
Emergency room visit for diabetes in past 6 months	
Day off work for diabetes in past 6 months	
Hypoglycemic episodes	

Eye examination	
Alcohol	
Last time a1c measured	
Urine protein screening	
Influenza vaccination	
Blood pressure management	
Aspirin use	
SMOKING	

. هل تعاني من أي مرض مزمن آخر؟ (اسم المرض والفترة الزمنية)

المرض	النوع/الفترة الزمنية	المرض	النوع/الفترة الزمنية

Appendix 2.Knowledge about drug therapy questionnaire (AbuRuz *et al.,* 2007e)

الأدوية المستخدمة حاليا لعلاج السكري؟ (موصوف, بدون وصفة, أعشاب)

4. هل تقوم باستخدام أي دواء بشكل مستمر؟ (موصوف, بدون وصفة, أعشاب)

الدواء (brand)	الجرعة	عدد مرات الاستخدام	مدة الاستخدام	أي تعليمات خاصة لاستخدام الدواء (الأكل, المضاعفات)	اخر مرة تناولت الدواء	المعرفة بالدواء	فعالية الدواء	آمنية (رأي المريض , المختبر)

Appendix 3. Medication adherence questionnaire

(AbuRuz *et al., 2007* a)

استبيان استخدام الدواء

الناس عادة يواجهون عدة مشاكل أثناء تناولهم لأدويتهم الموصوفة لتعددها واختلاف أوقاتها وأشكالها.نود أن نسألك بعض الأسئلة عن طبيعة استخدامك لدوائك.

		إطلاقا	نادرا	أحيانا	عادة	دائما
1	هل تنسى تناول دوائك؟					
2	هل تتوقف عن تناول دوائك من وقت لآخر؟					
3	هل تتوقف عن تناول دوائك عندما تشعر بتحسن؟					
4	هل تتوقف عن تناول دوائك إذا ساءت حالتك بعد أخذ الدواء؟					
5	هل تتوقف عن تناول دوائك إذا حصلت لك مضاعفات تعتقد أنها ناتجة عن استخدام الدواء؟					

Appendix4. THE SUMMARY OF DIABETES SELF-CARE ACTIVITIES

(AbuRuz *et al*., 2007b)

(يجب أن تكون الإجابة رقم يتراوح بين 0-7)

كم مرة خلال الاسبوع الماضي اتبعت حمية غذائيه صحيه

خلال الشهر الماضي كم يوما في الاسبوع اتبعت حميتك الغذائيه (كمعدل)

كم يوما في الاسبوع الماضي السابقة قمت بتناول خمس وجبات أو أكثر من الخضار والفواكه.

(الوجبة تعادل حبة واحدة من الخضار والفواكه).

كم يوما في الاسبوع الماضي قمت بتناول غذاء يحتوي على كمية عالية من الدهنيات

(حليب كامل الدسم ، لحوم حمراء).

في كم يوم من الأيام السبعة السابقة قمت بممارسة أعمال حركية متواصلة لمدة لا تقل عن30 دقيقة.

في كم يوم من الأيام السبعة السابقة قمت بممارسة أنواع خاصة من الرياضة (السباحة ،الركض، المشي) غير الذي تقوم به يوميا في بيتك أو عملك.

في كم يوم من الأيام السبعة السابقة قمت بقياس تركيز السكر في دمك

في كم يوم من الأيام السبعة السابقة قمت بقياس تركيز السكرفي دمك وفقا لعدد المرات التي اوصى بها الطبيب

في كم يوم من الأيام السبعة السابقة قمت بفحص قدميك

.في كم يوم من الأيام السبعة السابقة قمت بفحص حذاءك

كم عدد السجائر التي تقوم بتدخينها يوميا

تأثير تدخل الصيدلي السريري على النتائج الصحية لمرضى السكري

اعداد

محمد خلف اذويب

المشرف الرئيسي

د. نائلة بولاتوفا

مشرف مشارك

د. صلاح الدين ابو رز

مشرف مشارك

د. ايمن عارف زايد

الملخص

يبقى سوء التحكم بالسكري احد اهم العوامل المقلقة في المجال الصحي بسبب زيادة نسبة المصابين بالسكري ومضاعفاته. ارتفعت نسبة الاصابة بالسكري في الاردن بشكل كبير في الفترة ما بين 1994 و 2004، لذا هنالك احتمالية كبيرة لاستفادة المرضى من اي برنامج يهدف الى التحكم الجيد بالسكري والتقليل من مضاعفاته.

لقد تم تنفيذ عدة دراسات تهدف الى تقييم دور الصيدلي السريري. هذه الدراسات السابقة اما اشتملت على عدد قليل من المرضى، كانت غير عشوائية، استهدفت نوعية خاصة من المرضى كؤلائك الذين يستعملون الانسولين، او اصحاب السكر التراكمي العالي، لم تشتمل على مجموعة مقارنة، او لم تدرس عوامل ذات علاقة بالتحكم بسكر الدم.

الهدف من هذه الدراسة كان تقييم دور الصيدلي السريري المباشر في العناية بالمرضى وتأثيره على التحكم بالسكر وعوامل اخرى ذات علاقة عند المرضى المصابين بالنوع الثاني من ارتفاع سكر الدم.

النتيجة الرئيسية لهذه الدراسة هي ان تدخل الصيدلي السريري ادى الى تحسن ملحوظ وذو قيمة في النتائج الصحية لدى مرضى السكري مثل قياس السكر التراكمي، سكر الدم الصومي، والالتزام بالادوية وطريقة الحياة الصحية.